MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

Standard Operating Procedure (SOP) Manual

Approval Date: December 16, 2025

Effective Date: December 30, 2025

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

VISION

We are the nation's most trusted, caring and internationally-recognized healthcare institution with top-notch service, expertise and technology.

MISSION

To provide the highest quality healthcare experience for all stakeholders through:

1. Competent, compassionate, collegial, and ethical medical professionals and allied hospital personnel
2. Superior service delivery, enhanced by technological and digital innovations and supported by research
3. Sustained training/educational programs and other capacity-building initiatives; ethics based and responsive to evolving health challenges and global standards
4. Community responsive, collaborative, and socially empowering and environmentally sustainable healthcare programs.

VALUES

Service Excellence – providing competent, appropriate, safe & responsive health care services that result to: positive outcome, highest level of satisfaction of patient & colleagues.

Behavioral Statements:

- Delivers healthcare service on time.
- Defines objectives, identifies measures & implements strategies to deliver exceptional results.
- Follow-through & fulfills commitments made.
- Meets or exceeds the stakeholder's needs & expectations consistent with MMC policies.
- Constantly seeks innovative ways to improve the quality of service.

Integrity – Demonstrating sound moral and ethical principles at work; never compromising the name & ethical standards of the hospital.

Behavioral Value Statements:

- Continues to do the right thing even when no one is looking or watching.
- Communicates openly, honestly and truthfully with others.
- Takes accountability for own actions & decisions at all times.

Professionalism – Upholding the code of conduct of the Hospital & ethical standards of one's profession; consistently demonstrating competence in the performance ofone'sduties.

Behavioral Value Statements:

- Respects diversity (gender, ethnicity, religion, cultural & economic status).
- Inspires trust by delivering results at the highest level of professionalism.
- Learns rapidly and adapts quickly to changing situations,
- Willingly accepts additional responsibilities in the face of challenging situations.
- Strictly adheres to and complies with established policies, procedures, and standards.

Compassion – showing genuine concern and empathy through words and actions that leal to enhanced well-being of patients & colleagues.

Behavioral Statements:

- Always asks the patient about his/her condition and responds accordingly with kindness and encouragement.
- Acknowledges the patient's emotional state in the process of treatment.
- Goes the extra mile for the good of others and the organization.

Teamwork – collaborating harmoniously & respectfully with the team towards a common goal. Behavioral Statements:

- Encourages and values the ideas, expertise and contributions, including constructive criticism of all team members.
- Shares knowledge and expertise with team members.
- Holds team accountable for upholding MMC values.
- Provides the needed support and resources to achieve goals and objectives.
- Builds and maintains synergy with co-workers across the organization.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

INTRODUCTION

The Makati Medical Center Institutional Review Board (MMC-IRB) is an independent body created by the Makati Medical Center under the Medical Director. Its responsibility is to ensure the protection rights, safety and well-being of human subjects involved in health-related research and to provide public assurance of that protection.

In line with the Mission and Vision guidelines of MMC, the MMC-IRB functions as an independent, highly trained ethics review committee, reviewing and monitoring the conduct of research protocols to ensure the highest quality of expertise, healthcare and serve to all those involved in research associated with the institution.

The Makati Medical Institutional Review Board upholds the guiding principles of **Beneficence, Non-Maleficence, Respect for Persons and Justice** in the evaluation of research proposals and conduct of ongoing research studies under its jurisdiction. **As per MMC hospital policies and regulations** all health-related research involving human participants in the hospital as well as research conducted outside of the hospital by MMC personnel or Independent consultants and sites with a MOA, must go through the IRB review and approval process to ensure Scientific, Social and Ethical soundness of the research study. The principles of Beneficence, Respect for persons and Justice are applied in every review and evaluation of each research study to ensure:

- Risks to participants are minimized
- Risks to participants are reasonable in relation to anticipated benefit to ensure a positive benefit/risk ratio
- Selection of participants is equitable
- Informed consent is properly obtained and documented
- Adequate provision is made for monitoring the data collected to ensure the safety of participants
- Adequate provision is made to protect participants and maintain protection of data privacy and confidentiality of data
- Additional safeguards are included for vulnerable populations
- Social value of the study
- Adequacy of the investigators and the site where the research will be done

Hospital policy dictates that all health-related research involving humans cannot proceed until approved is secured by the MMC IRB. Once a research study has been approved, the investigators must abide by the post approval monitoring requirements and systems put in place by the IRB and regulatory bodies to ensure continued proper scientific and ethical ongoing conduct of the study. Continuing review of the study and any amendments to the initial study proposal is conducted by the IRB as long as the study remains active. Post approval monitoring includes proper and timely submission of amendments, yearly progress reports (unless requested more frequent) , protocol deviations and violations, reporting of SAE and notifications and reports of any relevant findings made known to the investigator and/or sponsors during the ensuing study process that may affect the welfare and safety of the human participants in the study.

In its effort to protect the study participants, the IRB constructed the Standard Operating Procedures (SOP) to guide its members, staff, and investigators who are planning to conduct a study protocol.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

The Makati Medical Center Institutional Review Board (MMC-IRB) - Standard Operating Procedures (SOP) Manual consists of the different processes practiced by IRB to accomplish its activities. The SOP is developed by the members and staff of MMC-IRB, using standard references such as Ethical Considerations, WHO Operational Guidelines, ICH-GCP, National Ethics Guidelines for Health Research, and FDA Policies.

The MMC-IRB SOP begins with the vision, mission and quality policy. The chapters are presented comprehensively for easy reference.

The IRB office is located at the 7th Floor Keyland Building, Tower 3, Makati Medical Center. Currently, it is composed of thirteen active members who are lay members and physicians with different medical expertise and age groups. Its organizational structure is also illustrated and defined in this SOP.

HISTORY

In 1987, the Makati Medical Center Institutional Review Board (MMC IRB) was formed in partnership with the Tropical Disease Foundation (TDF). In 2005, the MMC IRB and TDF separated into two district entities when TDF moved its operations to a new building. The MMC IRB became an independent committee under the Medical Education & Research Division of the Makati Medical Center (MMC). The Medical Education & Research Division was mandated by the MMC to serve as the executive/advisory body of the MMC IRB. In 2006, Dr. Saturnino P. Javier was appointed as Chair. In April 16, 2012, the MMC IRB was granted a certificate of registration by the Philippine Health Ethics Board (PHREB).

In 2013, the MMC IRB underwent several changes, such as establishing the MMC IRB as an independent office under the Medical Director, separate from the Medical Education and Research Division; development of a manual of Standard Operating Procedures; construction of a web portal that facilitates access and communication; provision of facilities, such as office space, secured storage for protocols, reference materials, computerized database and archiving documents; and addition of personnel to handle various aspects of implementation of clinical trials. It also provided Good Clinical Practice training the residents, fellows and consultants and hospital staff.

As it moves forward, the MMC IRB stays abreast with new developments in the field of technical and ethical research review. Simultaneously, the MMC IRB is promoting participation of more doctors and research staff in workshops and conferences to further uplift the quality of research in the institution.

MAKATI MEDICAL CENTER

Departmental General Operating Procedures

Chapter I: Institutional Review Board (IRB) Composition and Ethical Framework	Document Code: IRB-GOP-CEF-001	Rev. Code : 09
	Effective Date: December 30, 2025	Page 1 of 24

Issued by: Institutional Review Board	New ☑	Supersedes: IRB-GOP-1120-CEF-001 Rev. 08

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

This section defines the foundational structure and ethical underpinnings of the Makati Medical Center Institutional Review Board (MMC IRB). It establishes the principles, governance, and operational modalities that guide the IRB's composition, appointment processes, ethical oversight responsibilities, and adherence to regulatory standards. Grounded in international and national ethical guidelines, this framework ensures that the IRB is equipped with the appropriate multidisciplinary expertise and operates with transparency, integrity, and accountability in the protection of human research participants.

I. Objective:

This SOP aims to strengthen the governance and operations of the MMC IRB by defining its Terms of Reference in the following areas:

1.1. Constitution and structure of the IRB to ensure effective and credible ethical oversight.
1.2. Establishment of Confidentiality and Conflict of Interest Agreements for IRB members, the Secretariat, and independent consultants.
1.3. Implementation of a structured and continuous training program for IRB members and Secretariat staff.
1.4. Guidelines for the selection and engagement of qualified independent consultants.
1.5. Standardized service fee provisions for IRB members and consultants, ensuring equitable and transparent compensation.

II. Scope:

2.1. The MMC IRB is an independent review body constituted under the authority of the Medical Director to protect the rights, dignity, safety, and well-being of individuals participating in health and health-related research.

2.2. The IRB is empowered to review, approve, require modifications in, or disapprove research protocols and related documents. It also oversees the conduct of approved studies

and can impose restrictions, suspend, or terminate approval when necessary.

2.3. The IRB reviews research protocols involving:

2.3.1. Makati Medical Center patients, employees, trainees, and staff, including studies conducted on-site or in collaboration with non-affiliated organizations.

2.3.2. MMC active and associate staff conducting studies outside MMC premises.

2.3.3. Research conducted by external investigators in off-site locations covered by a valid Memorandum of Agreement with MMC IRB, which stipulates review, approval, and post-approval monitoring.

2.4. The MMC IRB reviews studies involving human participants. A review fee is generally applicable for externally funded research.

2.5. This SOP provides the Terms of Reference for the composition, responsibilities, and activities of the IRB members, officers, Secretariat, and consultants.

III. Responsibility

3.1. The Medical Director appoints the IRB Chair, members, and consultants based on the recommendation of the IRB Chair and consultation with current IRB members.

3.2. IRB members may nominate qualified independent consultants. Appointments are endorsed by the Chair to the Medical Director.

3.3. The IRB Secretariat provides administrative and technical support to the IRB.

3.4. The IRB Chair ensures that all new members undergo onboarding training, and that ongoing education is conducted for all IRB personnel.

3.5. The Secretariat develops and maintains a training plan and tracks competency development.

3.6. The IRB explores and recommends appropriate service fee structures for members and consultants, led by the Chair.

IV. Institutional Review Board (IRB) Composition and Ethical Framework

4.1 Ethical Basis

MMC IRB's decisions are guided by the ethical principles and procedures set forth in the following documents:

a. Declaration of Helsinki (2024)
b. CIOMS Guidelines (2016)
c. WHO Operational Guidelines for Ethics Committees (2000)
d. WHO Standards and Operational Guidance (2011)
e. ICH-GCP E6(R3) 2025
f. National Ethical Guidelines for Health and Health-Related Research (NEGHHR 2022)
g. PHREB Accreditation Policies and Requirements
h. Philippine National Health Research System (PNHRS) Act of 2013
i. FDA Philippines and relevant local and international regulations
j. WHO tool for benchmarking ethics oversight of health-related research involving human participants 2023

4.2 Ethical Review Jurisdiction

MMC IRB acknowledges that protocols approved may also undergo review by local or national ethics bodies. The IRB maintains awareness of applicable laws, cultural contexts, and sponsor requirements, especially for multi-site and international studies.

4.3 Guiding Principles

a. Upholds participant autonomy, safety, and welfare.
b. Applies ethical principles consistently across all reviews.
c. Maintains independence, integrity, and transparency in all operations.
d. Considers scientific soundness alongside ethical merit.
e. Remains responsive to emerging ethical challenges including data privacy, community engagement, and AI-driven research.

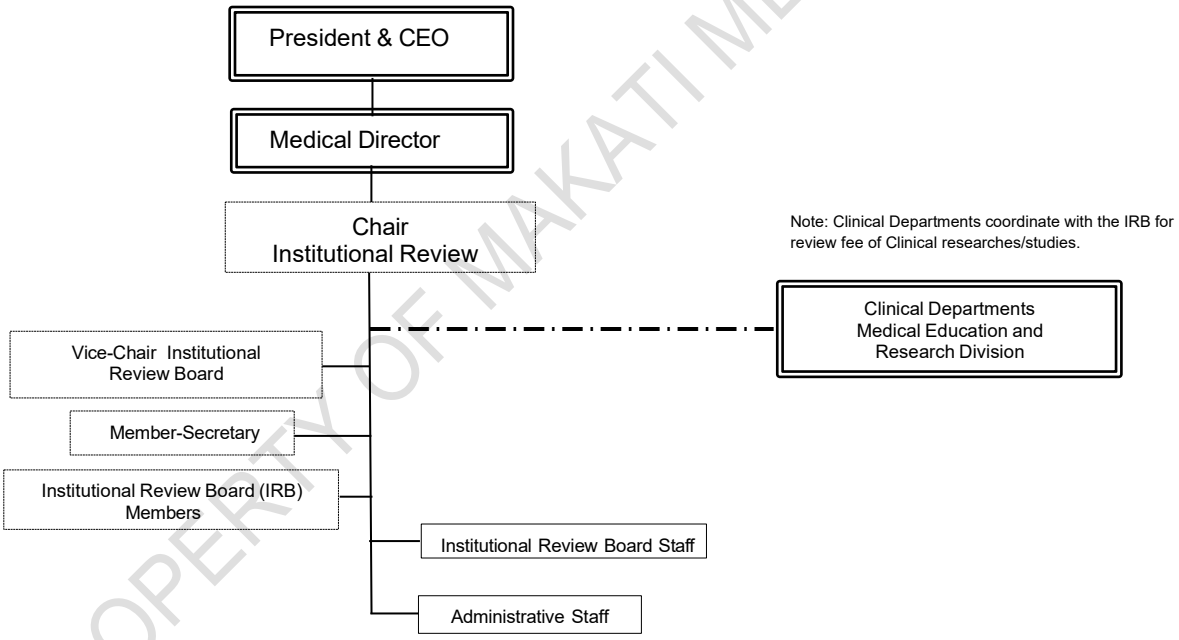
V. Constitution - Organizational Structure

5.1 Appointment and Authority - The Institutional Review Board (IRB) of Makati Medical Center is constituted under the authority of the Medical Director, who serves as the appointing officer. The Medical Director appoints the IRB Chair, Vice Chair, Member-Secretary, and regular members based on recommendations from the IRB Chair and consultation with the current Board. Appointments ensure multidisciplinary representation and operational functionality of the IRB.

5.2 Organizational Structure - The MMC IRB operates under the following chain of authority:

- **Medical Director** – Appointing authority, institutional oversight
- **IRB Chair** – Recommending officer, leads IRB deliberations and strategic direction
- **IRB Vice Chair** – Assists and deputizes for the Chair in their absence
- **Member-Secretary** – Head of the IRB Secretariat; a voting IRB member; coordinates administrative functions and ensures documentation
- **IRB Members** – Composed of medical, non-medical, legal, social science, and lay representatives to ensure well-rounded ethical evaluation
- **IRB Secretariat** – Provides administrative and technical support to the Board

A visual organizational chart shall accompany this section (see *Annex A*), outlining the reporting and functional relationships among IRB stakeholders.



5.3 Institutional Linkages and Collaboration - The MMC IRB collaborates with research committees across clinical departments. These departmental committees are responsible for the technical review of protocols submitted by residents and fellows. The Head of the

departmental research committee or designated research adviser endorses technically approved protocols to the IRB for ethical review. The IRB Secretariat verifies the completeness of the required documentation prior to scheduling review.

5.4 Review of Protocols - For externally sponsored or investigator-initiated studies not affiliated with department research committees, the MMC IRB conducts both technical and ethical reviews to ensure scientific merit and participant protection.

5.5 Dissolution Clause - Only the MMC Medical Director has the authority to dissolve the MMC IRB, subject to due process and proper documentation. In the event of IRB dissolution, all associated subcommittees, including SPARES (Subcommittee Panels for Minimal Risk Research Protocols), are automatically disbanded.

VI. Quorum Requirements

6.1. The MMC IRB strictly adheres to quorum requirements prescribed by national and international ethics guidelines (e.g., NEGHHR 2022, CIOMS, ICH-GCP). A quorum must be established to conduct a review and make decisions validly during convened meetings.

6.2. A quorum is considered present when the following conditions are met:

- At least **50% plus one** of the total IRB memberships is in attendance.
- At least **one lay member** and **one non-affiliated member** are present.
- For protocols involving pediatric populations, a **pediatrician or child development expert** must be in attendance.

6.3. If quorum is not met at any point during the meeting, the IRB must defer further discussion and decisions until quorum is re-established.

VII. Decision-Making Process

7.1. Following the review and discussion of each protocol, the IRB summarizes its key comments, required revisions, and recommendations before voting on a final decision.

7.2. A decision is made through formal voting. A majority vote (50% + 1 of members present) is required for approval or disapproval. Each vote is recorded as “For,” “Against,” or “Abstain.”

7.3. While unanimity is not required, all members must accept the majority decision as final. Dissenting votes are documented, and abstentions are not counted toward the decision.

7.4. Members with a declared conflict of interest are not allowed to vote and are excluded from quorum for that specific protocol.

VIII. Appeal of MMC IRB Decisions

8.1. A sponsor or Principal Investigator (PI) may appeal a disapproval decision by submitting a formal **Letter of Appeal** to the IRB Chair, outlining the justification for reconsideration.

8.2. The appeal must be accompanied by a **revised protocol** incorporating the changes requested by the IRB.

8.3. The revised documents are reviewed by the full board during a convened meeting.

8.4. The full board shall deliberate and issue a final decision on the appeal, which may be **approval**, **conditional approval**, or **disapproval**.

8.5. The IRB's decision on the appeal is **final and non-appealable**.

IX. Conflict of Interest and Confidentiality Agreement

9.1. All MMC IRB members, Secretariat staff, Independent Consultants, and Guest Reviewers are required to sign the **Confidentiality and Conflict of Interest Agreement** (Form 1.3A or 1.3B) prior to participation in IRB activities.

9.2. The agreement ensures the protection of confidential information related to research protocols, meeting deliberations, study participants, and institutional records.

9.3. The IRB Secretariat shall issue the agreement forms along with appointment letters and retain one signed copy in the member's file. The second copy is for the member's reference.

9.4. Agreements must be signed:

- Upon initial appointment, and
- Annually at the start of each calendar year.

9.5. It is the member's responsibility to read, understand, and comply with the agreement before undertaking ethical review responsibilities.

9.6. A refusal to sign the agreement constitutes grounds for disqualification or discontinuation of IRB membership or consultancy.

9.7. All IRB members must proactively **disclose any actual, potential, or perceived conflicts of interest** prior to the review and discussion of any agenda item.

9.8. The IRB, through the Chair, will determine appropriate actions to manage the declared conflict, which would include:

- Recusal from voting
- Removal from deliberations
- Attendance as a resource person only

* Prior to the discussion of the review or agenda item, the Chair will request the secretariat to remove the member from the meeting. Once the discussion and voting are complete, the IRB member can be returned to the meeting upon the order of the Chair. Documentation of removal and time of entry will be recorded in the minutes.

9.9. A conflicted member may be allowed to present the protocol (if the PI or adviser) but must exit the room before deliberations begin. That member is excluded from the quorum and voting for that specific protocol.

9.10. If the **Chair** declares a conflict of interest, he or she must **designate the Vice Chair or another qualified member** to lead the proceedings for that agenda item. This will be documented in the meeting minutes.

9.11. Investigators are prohibited from selecting IRB members for the review of their protocols.

9.12. Newly appointed members shall receive **two copies** of the Confidentiality and Conflict of Interest Agreement—one for personal retention and one for filing in the official IRB records.

X. Appointment and Composition of IRB Members

10.1. Nomination and Appointment Process

10.1.1. Nomination Procedures

10.1.1.1. The IRB Chair or Secretariat shall initiate the nomination process by requesting current IRB members to recommend potential candidates for membership.

10.1.1.2. Nominations are submitted to the IRB Chair for evaluation of the nominee's qualifications.

10.1.1.3. The IRB Chair submits a list of qualified nominees to the Medical Director for consideration.

10.1.1.4. The Medical Director, as the appointing authority, selects and formally appoints IRB members and independent consultants.

10.1.1.5. Upon appointment, each new member shall:

- Receive a copy of the IRB Member Job Description

- Sign the Confidentiality and Conflict of Interest Agreement (Form 1.3A)
- Submit a signed and updated Curriculum Vitae (Form 1.2)

10.1.1.6. The IRB Secretariat shall securely file all submitted documents in the IRB member's official records.

10.2. Membership Requirements

10.2.1. The MMC IRB shall consist of no fewer than **nine (9) members**.

10.2.2. The composition must be **multidisciplinary** and **multi-sectoral**, ensuring diverse perspectives.

10.2.3. Membership must include:

- Persons with primary concerns in medical science
- At least one pediatrician or child development expert
- At least one member from a non-medical, non-scientific field
- At least one **non-affiliated member** (not employed or otherwise connected with MMC)

10.2.4. The composition shall reflect a broad range of professional and community perspectives to facilitate comprehensive and context-sensitive protocol reviews.

10.2.5. Areas of expertise may include medicine, public health, law, behavioral and social sciences, ethics, nursing, pharmacology, and environmental science.

10.2.6. The IRB aims for **gender balance** and generational diversity.

10.2.7. Independent consultants may be engaged when additional expertise is necessary for the ethical review of specialized protocols.

10.3. Member Qualifications

10.3.1. All members must possess good moral character, relevant ethical and/or scientific knowledge, and a commitment to the IRB's mandate

10.3.2. Members should have prior training in:

- Good Clinical Practice (GCP)
- Research methodology
- Research ethics
- Undergo SOP orientation. Certification of SOP orientation issued after training and filed in members files.

10.3.3. All members are required to submit written disclosures of any personal, professional, or financial conflicts of interest.

10.3.4. Members are appointed initially for one (1) year, with reappointment for a two (2)-year term based on performance and recommendation.

10.3.5. Members shall submit annually updated and signed Curriculum Vitae (Form 1.2).

10.3.6. All members must sign the Confidentiality and Conflict of Interest Agreement (Form 1.3A) upon appointment and annually thereafter.

10.4. Conditions of Appointment

10.4.1. Appointees must be willing to:

- Make public their full name, professional background, and institutional affiliation as IRB members.
- Disclose financial relationships, reimbursements, or compensations received in relation to IRB activities, as required for transparency.
- Adhere to the **Confidentiality and Conflict of Interest Agreement**, covering protocol documents, deliberations, and all related research matters.

10.5. Terms of Appointment and Responsibilities

10.5.1. The Job Description issued to appointed members shall detail:

- Functions and scope of work
- Terms of office
- Conditions for replacement or recall
- Provisions for compensation, if any

10.5.2. Terms of Appointment:

- IRB Members and Consultants:
  - Initial term: 1 year
  - Reappointment: 2 years
- Chair: 4-year fixed term
- Vice Chair: 3-year fixed term
- Member-Secretary:
  - Initial term: 1 year
  - Reappointment: 2 years

10.5.3. The Medical Director may renew appointments upon recommendation of the IRB Chair.

10.5.4. The IRB maintains a rotation system to allow new perspectives while preserving institutional memory and expertise.

10.5.5. The Medical Director retains final authority on all appointments and renewals.

10.6. Types of IRB Members

Member Category	Description
Medical / Scientific Members	Licensed physicians or health professionals with research expertise
Non-Medical / Scientific Members	Professionals from health-allied fields (e.g., nursing, pharmacy, paramedical)
Non-Medical / Non-Scientific Members	Laypersons with no medical or scientific training, representing community interests
Independent Consultant	Designated independent consultants are available to provide substitute or advisory support as required.
Non-affiliated Lay Members	Laypersons non affiliated with MMC (not employed or otherwise connected with MMC

XI. Roles and Responsibilities of MMC IRB Officers and Members

11.1. IRB Chair

- The Chair leads the operations of the MMC Institutional Review Board and is directly accountable to the Medical Director. The Chair's responsibilities include:

11.1.1. Presides over all MMC IRB meetings.

11.1.2. Represents the MMC IRB within the hospital and to external stakeholders

11.1.3. Prepares and submits the **Annual IRB Report** to the Medical Director, summarizing decisions, operations, and achievements.

11.1.4. Ensures availability of financial and administrative resources for effective IRB operations.

11.1.5. Submits the **annual operating budget** for the IRB to the Medical Director for approval.

11.1.6. Makes initial determinations on whether a protocol is eligible for expedited review or requires full board deliberation.

11.1.7. Oversees overall compliance of the IRB with national and international **Good Clinical Practice (GCP)** standards.

11.2. IRB Vice Chair

- The Vice Chair assumes the duties of the Chair when delegated or in the Chair's absence. Responsibilities include:

11.2.1. Presides over IRB meetings when designated.

11.2.2. Assists in preparing and reviewing annual reports and budget proposals.

11.2.3. Supports representation of the IRB in administrative and external engagements.

11.2.4. Collaborates with the Chair in determining appropriate review pathways for protocols.

11.2.5. Monitors institutional compliance with GCP and IRB policies.

11.3. Member-Secretary

- The Member-Secretary is both a voting member and the administrative head of the IRB Secretariat. The Member-Secretary is responsible for:

11.3.1. Managing and supervising the IRB Secretariat.

11.3.2. Recommending the appropriate review pathway (expedited or full board) for protocols to the Chair.

11.3.3. Assigning primary and guest reviewers with Chair approval.

11.3.4. Ensuring accurate documentation and secure archiving of IRB files.

11.3.5. Consolidating and presenting post-approval submissions (e.g., amendments, SAEs, deviations) to the full board.

11.3.6. Ensuring the IRB department's compliance with hospital governance, accreditation, and regulatory standards.

11.3.7. Supporting the operational and technical needs of the IRB Chair.

11.3.8. Conducting performance evaluations and providing feedback to IRB Secretariat staff.

11.3.9. Performing additional tasks assigned by the IRB Chair.

11.4. Regular IRB Members

11.4.1. Regular members fulfill core responsibilities of protocol review and ethical oversight. They are expected to:

11.4.1.1. Attend and actively participate in IRB meetings.

11.4.1.2. Maintain confidentiality of IRB documents, data, and deliberations.

11.4.1.3. Disclose any conflict of interest prior to discussions.

11.4.1.4. Review, discuss, and vote on submitted research protocols.

11.4.1.5. Evaluate scientific soundness (for medical members) or participant protection (for non-medical/lay members).

11.4.1.6. Assess serious adverse event (SAE) reports and recommend action.

11.4.1.7. Review study progress, post-approval monitoring reports, and final reports.

11.4.1.8. Engage in continuing education on research ethics and human participant protection.

11.4.1.9. Carry out other assignments as designated by the IRB Chair**.**

11.5. Independent Consultants

11.5.1. Independent consultants serve on a flexible basis, contributing their expertise when needed. Their responsibilities include:

- Attend IRB meetings at least four times annually or as required.
- Review, discuss and vote on their respective protocols, with emphasis on scientific merit or informed consent component
- Maintain confidentiality of IRB deliberations and materials.
- Assess SAE reports and contribute to post-approval monitoring reviews as needed**.**

11.6. Adverse Events Subcommittee (AES)

- The AES oversees the review of serious adverse events (SAEs) related to MMC IRB-approved studies. The AES is composed of:

- One Chair and two members appointed by the IRB Chair.
- At least one member with expertise in pharmacology or clinical pharmacy.

Key responsibilities include:

11.6.1. Review of all on-site SAE reports submitted by investigators.

11.6.2. Provide recommendations regarding SAE assessments to the full board on a monthly basis.

11.6.3. Present a summary of SAE reports to the IRB at scheduled board meetings.

11.7. Subcommittee Panels for Minimal Risk Research Protocols (SPARES)

11.7.1. **Structure and Assignment**

- SPARES are designated subcommittees assigned to review minimal-risk research.
- Each Spares subcommittee is comprised of at least two members:
  - One medical board member
  - One non –medical board member

11.7.1.1. The IRB Chair determines the **composition of each subcommittee**.

11.7.1.2. Number of SPARES subcommittee Panels is determined by the IRB Chair based on the need and availability of board members.

11.7.1.3. Research coordinators or subject matter experts may be invited to a SPARES subcommittee by the IRB Chair as **temporary reviewers** when necessary.

11.7.2. **Function and Scope**

11.7.2.1. SPARES conduct initial review, ethical evaluation, and provide recommendations for minimal-risk protocols, in alignment with IRB policies.

11.7.2.2. Each member of the subcommittee reviews the protocol independently and submits a protocol evaluation form 2.7B.

11.7.2.3. The spares subcommittee meets monthly in a virtual platform to discuss the protocols assigned to that group.

11.7.2.4. The subcommittee Evaluate the scientific soundness (for medical members) or participant protection (for non-medical/lay members).

11.7.2.5. The members will then render a recommendation in alignment with IRB Policies. Decision points include approval, minor or major modifications or disapproval.

11.7.2.6. Protocols given major modification are then elevated and presented in a subsequent full board meeting.

11.7.2.7. Review study progress, post-approval monitoring reports, and final reports.

11.8. Adverse Events Subcommittee (AES)

11.8.1. **Structure and Purpose**

11.8.1.1. The Makati Medical Center Institutional Review Board (MMC IRB) Adverse Events Subcommittee (AES) is responsible for reviewing and assessing all adverse events associated with IRB-approved protocols.

11.8.2. **The AES shall be composed of:**

- One (1) Subcommittee Chair
- Two (2) AES Members, Appointed by the IRB Chair.

11.8.2.1. At least one AES member must have a strong pharmacology or clinical pharmacy background to ensure competent evaluation of drug-related adverse events.

11.8.3. **Responsibilities**

11.8.3.1. AES reviews all on-site Serious Adverse Event (SAE) reports submitted for IRB-approved protocols.

11.8.3.2. AES submits its recommendations and safety assessments to the full board on a monthly basis.

11.8.3.3. AES provides a summary re

11.8.3.4. port of reviewed SAEs during scheduled IRB meetings.

11.9. Resignation, Disqualification, and Replacement of IRB Members

11.9.1. An MMC IRB member may resign at any time by submitting a formal **Letter of Resignation** addressed to the IRB Chair, with a copy furnished to the Medical Director.

11.9.2. A member may be disqualified for the following valid reasons, subject to a **majority vote** of the IRB:

11.9.3. Refusal to sign the **Confidentiality and Conflict of Interest Agreement (Form 1.3A)**.

11.9.4. Breach or non-compliance with the signed Confidentiality and COI Agreement.

11.9.5. Absence from **three (3) consecutive IRB meetings** without submitting a formal leave of absence.

11.9.6. Repeated non-compliance with roles and responsibilities as defined in the MMC IRB SOP.

11.9.7. Vacancies due to resignation or disqualification shall be filled in accordance with the **nomination and appointment procedures** outlined in Section XI of this SOP.

11.9.8. The appointed replacement member shall serve for the **remainder of the unexpired term** of the outgoing member.

11.10. Process Flow Map:

NO	ACTIVITY	RESPONSIBILITY
1	Ask the MMC IRB members to nominate potential new members.	Chair
2	Submit names of potential members to the Chair.	Member/ IRB Secretariat
3	Recommend and submit a list of potential members to the Medical Director	Chair/ IRB Secretariat
4	Appoint new MMC IRB members	Medical Director
5	Receives **Job Description - Member** and signs Confidentiality and Conflict of Interest Agreements **(Form 1.3A)** and submit updated Curriculum Vitae **(Form 1.2)**	New Members
6	Files documents	IRB Admin Staff

XII. Selection, Responsibilities, and Termination of Independent Consultants

12.1. Selection of Independent Consultants

12.1.1. Request and Nomination

12.1.1.1. The IRB Chair or Secretariat may initiate a request for Independent Consultant(s) when specialized expertise is required for a protocol under review.

12.1.1.2. MMC IRB members or the IRB Secretariat may nominate qualified consultants to assist in the evaluation of research where the IRB lacks sufficient expertise.

12.2. Screening and Recommendation Process

12.2.1. The IRB Secretariat compiles and maintains a roster of prospective consultants, organized by area of specialization.

12.2.2. The IRB Chair and/or Member-Secretary review the qualifications of nominated consultants.

12.2.3. The IRB Chair finalizes the shortlist based on expertise, availability, and willingness to participate, and submits it to the Medical Director for appointment.

12.3. Appointment

12.3.1. The Medical Director formally appoints selected Independent Consultants.

12.3.2. The appointment is valid for **one (1) year** for first-time consultants and **two (2) years** for succeeding appointments.

12.3.2.1. Required Documentation - Upon appointment, the Independent Consultant must submit the following:

- Updated **Curriculum Vitae** (Form 1.2)
- Signed **Terms of Reference** (Form 1.1A)
- Signed **Confidentiality and Conflict of Interest Agreement** (Form 1.3B)
- Valid **Good Clinical Practice (GCP) Certificate**
- Any other required credentials relevant to their field of expertise

12.3.2.2. The IRB Admin Staff files all documentation in the **Independent Consultant folder**, organized **alphabetically by specialization**.

12.4. Responsibilities of Independent Consultants

12.4.1. Review assigned study protocols and provide written assessments.

12.4.2. Complete the appropriate Assessment Forms (Forms 2.7B and 2.8), which become part of the permanent study file.

12.4.3. Attend IRB meetings when invited to present assessments and participate in discussions, without voting rights or being counted toward quorum.

12.4.4. Recommend protocol revisions or endorse the protocol for full board review and deliberation.

12.5. Termination of Services

12.5.1. The services of an Independent Consultant may be terminated by:

- 16.8.1.1. The consultant (voluntary resignation), or
- 16.8.1.2. The MMC IRB, due to non-performance, conflict of interest breaches, or lack of need for specific expertise.

12.5.2. Upon termination, the IRB Secretariat shall:

- 16.8.2.1. Record the termination in the consultant's file, and
- 16.8.2.2. Ensure that all submitted documentation remains archived as part of IRB records**.**

12.6. Process Flow Map:

NO.	ACTIVITY	RESPONSIBILITY
1	Request for independent consultants.	Chair
2	Submit name of the potential consultants to the Chair.	Members/ IRB Secretariat
3	Selects and recommends list of consultants to the Medical Director.	Chair
4	Appoints new MMC IRB Consultant(s).	Medical Director
5	Receives appointment letter and sign Confidentiality and Conflict of Interest Agreements **(Form 1.3B)** and submit updated Curriculum Vitae (CV) and Good Clinical Practice Certificate (GCP) **(Form 1.2)**	New members/ Officer/ Consultants
6	Files documents.	IRB Admin Staff

XIII. IRB Secretariat and Administrative Staff

13.1. IRB Secretariat

13.2. Qualifications

- The IRB Secretariat staff must meet the following minimum qualifications:

13.2.1. A graduate of BS Nursing or any allied health science-related course; GCP training is preferred.

13.2.2. Computer literate and proficient in standard office software.

13.2.3. Demonstrated skills in coordination, project management, communication (oral and written), archiving, and organization.

13.2.4. Must sign the **Conflict of Interest and Confidentiality Agreement** (Form 1.3A).

13.2.5. Must submit an updated **Curriculum Vitae** (Form 1.2).

13.3. Functions of the IRB Secretariat

- The IRB Secretariat is responsible for the following tasks to support the operations and compliance of the MMC IRB:

13.3.1. Verifies that all studies adhere to Good Clinical Practice (GCP), prioritize participant safety, and ensure data integrity.

13.3.2. Receives and processes initial and resubmitted research protocols from investigators or sponsors.

13.3.3. Reviews submitted protocols for **completeness and compliance** with IRB submission requirements.

13.3.4. Coordinates with the IRB staff regarding records management and documentation.

13.3.5. Updates and maintains the IRB database and institutional IRB website.

13.3.6. Provides regular updates to the IRB Chair regarding the status of ongoing protocols.

13.3.7. Assists in **post-approval monitoring** of research protocols.

13.3.8. Tracks the status of approved protocols, including:

- Dates of submission, review, revision, and approval
- Study start and end dates
- Interim analysis, if applicable

13.3.9. Monitors all **adverse event reports** and immediately flags **serious adverse events (SAEs)** for IRB review.

13.3.10. Prepares documentation and reports such as:

- Interim analysis results
- Study withdrawals
- Dropout rates
- Health alerts and advisories
- Amendments and protocol updates
- End-of-trial reports

13.3.11. Attends the **Medication Safety Subcommittee meetings** and reports onsite SAEs.

13.3.12. Attends monthly IRB meetings; prepares meeting agendas, transcribes minutes, and provides admin support.

13.3.13. Maintains and updates administrative files and related IRB documentation.

13.3.14. Oversees the preparation, revision, and distribution of **IRB SOPs and guidelines**.

13.3.15. Prepares and updates the **IRB Quality Manual** and supporting documents.

13.3.16. Assists in organizing IRB-led seminars, workshops, and institutional training events.

13.3.17. Stays abreast of best practices in IRB systems and clinical study oversight by attending required CME activities.

13.3.18. Conducts IRB orientation for trainees, investigators, and other stakeholders.

13.3.19. Participates in **quality improvement initiatives** of the IRB.

13.3.20. Performs other duties assigned by the Chair or Member-Secretary as necessary.

13.4. IRB Administrative Staff

13.4.1. **Functions of the IRB Administrative Staff**

- The IRB Administrative Staff supports the day-to-day operations of the IRB through the following:

13.4.1.1. Acts as the **Document Custodian** and maintains the IRB's physical and electronic filing systems.

13.4.1.2. Prepares and sends all official IRB correspondence (e.g., letters, memos, invitations).

13.4.1.3. Organizes and archives documents, protocol submissions, and IRB databases.

13.4.1.4. Maintains a reference library of ethical guidelines, books, and regulatory references.

13.4.1.5. Receives and handles all incoming submissions from pharmaceutical companies and investigators.

13.4.1.6. Distributes protocols and relevant documents to IRB members and external bodies (e.g., PHREB).

13.4.1.7. Responds to inquiries related to IRB protocol submission processes.

13.4.1.8. Assists in IRB meetings and events:

- Coordinates venue, technical setup, and catering
- Supports IRB officers and members during sessions

13.4.1.9. Monitors office supplies and financial transactions of the IRB.

13.4.1.10. Facilitates **payment of IRB review and Clinical Trial Agreement (CTA) fees**.

13.4.1.11. Prepares statements of account and tracks the IRB's financial status.

13.4.1.12. Drafts the **annual IRB budget** for institutional approval.

13.4.1.13. Manages attendance and **honoraria processing** for IRB members and guest reviewers.

13.4.1.14. Processes supply requisitions and maintains procurement records.

13.4.1.15. Obtains IRB supplies and logistical requirements from relevant departments.

13.4.1.16. Assists in the facilitation of IRB-led training, workshops, and CME events.

13.4.1.17. Monitors and documents training sessions completed by IRB members and staff.

13.4.1.18. Prepares and updates **appointment letters** for IRB members and reviewers.

13.4.1.19. Updates and maintains IRB-assigned laptops and other digital tools.

13.4.1.20. Participates in continuous quality improvement activities of the IRB.

13.4.1.21. Performs other administrative duties as assigned by the immediate superior.

XIV. Training and Continuing Education

14.1. Makati Medical Center (MMC) recognizes that the competence of its Institutional Review Board (IRB) members and Secretariat is critical to maintaining high ethical and scientific standards in protocol review and oversight. This Standard Operating Procedure (SOP) outlines the training and continuing professional development requirements for all MMC IRB members and Secretariat staff.

14.2. Initial Training Requirements

- All newly appointed MMC IRB members and Secretariat staff must undergo initial training before participating in protocol review or operational activities. The required components include:

14.2.1. Basic Research Ethics Training: Covering core ethical principles in human research protection.

14.2.2. Good Clinical Practice (GCP): Formal certification, valid for three (3) years.

14.2.3. In-House Orientation: Focused on MMC IRB Standard Operating Procedures, forms, and administrative processes.

14.3. Continuing Education and Competency Maintenance

- Continuing education is required to maintain and update the knowledge and competency of IRB members and staff. The following mechanisms shall be implemented:

14.3.1. The Secretariat monitors the expiration dates of GCP certificates and informs individual IRB members in advance.

14.3.2. The Secretariat regularly tracks and disseminates training opportunities (e.g., courses, webinars, workshops, and conferences) via bulletin boards, emails, and circulars.

14.3.3. External training opportunities shall be made available at least once a year to both IRB members and Secretariat staff.

14.3.4. The MMC IRB shall ensure sufficient budgetary support to enable participation in approved training activities.

14.3.5. The Secretariat coordinates attendance and logistics when MMC IRB members are scheduled to attend external training.

14.4. Training Request and Endorsement Procedure

14.4.1. Any MMC IRB member or staff interested in attending a training activity must submit a written request to the IRB Chair at least one (1) month prior to the event.

14.4.2. The request must include supporting documents such as a registration form, program agenda, or official invitation.

14.4.3. The IRB Chair will evaluate the request, recommend participation, and endorse the request to the Medical Director for approval.

14.5. Continuing Education Content Areas

14.5.1. MMC IRB members and Secretariat staff are expected to maintain competence in the following areas, with content updated as applicable:

- Good Clinical Practice (GCP) – Certification renewed every 3 years
- Declaration of Helsinki (latest version)
- Council for International Organizations of Medical Sciences (CIOMS) Guidelines
- Philippine National Ethical Guidelines and other ethical standards
- Relevant Laws and Regulations related to research ethics and clinical trials
- Scientific and Regulatory Developments relevant to human research protection
- International Conferences on research ethics, health research, and data protection
- MMC IRB Standard Operating Procedures and institutional policies

14.6. Safe-Keeping of training records

14.6.1. Attendance sheets of in-house training with relevant information about the topic, duration, date and venue are prepared and filed accordingly.

14.6.2. Curriculum Vitae and Training Record (Form 1.2) of individual member/ IRB Secretariat are updated to reflect attendance of training activities. *Photocopy of certificates is filed when possible. Training records of IRB members and IRB Secretariat are kept in the membership and IRB Secretariat files.

14.7. Process Flow Map:

NO.	ACTIVITY	RESPONSIBILITY
1	Provide initial training for new MMC IRB members and staff.	Chair/ IRB Secretariat
2	Keep track of training needs of MMC IRB members and staff and plan for continuing education.	Member/ IRB Secretariat
3	Watch out for training opportunities.	Member/ IRB Secretariat
4	Signify intention to attend training program/ workshop/ seminars	Member/ IRB Secretariat / IRB Chair
5	Attend in-house and external training	Member/ IRB Secretariat
6	Keep training records of the MMC IRB members and staff (Form 1.2).	IRB Admin Staff

XV. Service Fees for the MMCIRB Members and Consultants

15.1. MMC IRB acknowledges the time, effort, and professional expertise required of its members and independent consultants in fulfilling their duties. This section outlines the procedures for the recommendation, approval, and disbursement of service fees for IRB-related work.

15.1.1. The IRB Chair shall explore available financial and administrative mechanisms to support the provision of service fees or honoraria to MMC IRB members and consultants. This includes reviewing institutional policies and PHREB-accredited precedents.

15.1.2. The Chair shall include the proposed service fee structure or updates as an agenda item during MMC IRB meetings for review and deliberation by the Board.

15.1.3. MMC IRB members may endorse, revise, or recommend alternative schemes for service fees during the discussion. Final recommendations shall be agreed upon through Board consensus.

15.1.4. The IRB Chair shall submit the service fee proposal (or adjustment) to the Medical Director for budgetary approval as part of the annual IRB operating plan.

15.1.5. The Medical Director reviews and decides on the Chair's recommendation and may either approve or disapprove the proposed service fees.

15.1.6. Once approved, MMC IRB members and consultants shall be formally informed of the fee structure, and the IRB Administrative Staff shall coordinate the disbursement of approved service fees or honoraria.

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

Signatories:

Author (s)	**Carolyn A. Butler, MD** Institutional Review Board **Joshua Jaime P. Nario, DLGHCO, MA, RN** IRB Member-Secretary Institutional Review Board **Rocelle F. Surat, CLSSYB** IRB Assistant Institutional Review Board
Reviewers	

MAKATI MEDICAL CENTER

Departmental General Operating Procedures

Chapter II: Initial Protocol Review and Approval	Document Code: IRB-GOP-IPR-002	Rev. Code : 09
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Issued by: Institutional Review Board	New ☑	Supersedes: IRB-SOP-1120-IPR-002-08

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

The ethical and scientific review of research protocols is a fundamental function of the Makati Medical Center Institutional Review Board (MMC IRB). As per MMC institutional policies and international ethical guidelines, any health-related research involving human subjects cannot commence until approval of the research protocol is provided by the MMCIRB. This chapter outlines the standardized procedures for the initial review and approval of research proposals, ensuring that all studies involving human participants comply with national regulations, institutional policies, and international ethical guidelines.

I. Objectives:

This chapter outlines the procedures and standards for the initial review of research protocols submitted to the Makati Medical Center Institutional Review Board (MMC IRB). The objectives are to:

1.1. Define the process from submission to acknowledgment of protocols by the Principal Investigator (PI).

1.2. Establish the criteria for determining the type of review: Full Board, Expedited, or Minimal Risk (SPARES).

1.3. Describe the role of the IRB Secretariat in managing submissions and maintaining electronic records.

1.4. Detail the evaluation process for scientific, technical, and ethical soundness.

1.5. Explain procedures for different types of review:

- 1.5.1. Full Board Review
- 1.5.2. Expedited Review
- 1.5.3. Minimal Risk Protocol Review (SPARES)

1.6. Outline procedures for reviewing medical device protocols based on risk level.

1.7. Provide guidance for reviewing compassionate use requests, including eligibility and decision criteria.

1.8. Ensure alignment with international WHO guidelines and as well as PHREB Resolution No. 20-001 for COVID-19-related studies and any pandemic related studies.

1.9. Safeguard the rights, welfare, and safety of study participants, researchers, and IRB personnel.

1.10. Establish guidelines for electronic submissions and virtual IRB review meetings.

1.11. Clarify procedures for parallel review coordination with the Single Joint Research Ethics Board (SJREB).

1.12. Identify the target users of this chapter, including MMC-affiliated researchers, IRB members, and Secretariat staff.

II. Scope:

II.1. This SOP applies to all initial research protocol submissions requiring ethical review by the MMC IRB and includes studies conducted:

2.1.1. Within MMC premises, or

2.1.2. Outside MMC by active, associate active, or house staff.

2.1.3. Outside MMC by outside investigators with MOA with MMC.

2.2. This chapter covers all types of protocol submissions and the IRB's corresponding review responsibilities.

2.3. Standard Evaluation Tools:

2.3.1. *Protocol Evaluation Forms:*

- Form 2.7A (Protocol Information)
- Form 2.7B (Protocol Evaluation)
- Form 2.8 (Informed Consent Evaluation)

2.3.2. *Informed Consent Evaluation Form:* Form 2.8

2.4. Types of Review Covered:

2.4.1. All health-related research protocols for Initial submission

2.4.2 All health-related research protocols for Resubmission

2.4.3. Minimal risk protocols and those with minor revision

2.4.2. Modified protocols previously reviewed by the full board and downgraded for expedited review

2.4.3. Medical device studies based on risk level: Significant Risk (SR) or Non-Significant Risk (NSR)

2.4.4. Revised protocols, consent forms, and IRB responses

2.4.5. Compassionate use protocols for diagnostics or therapeutics

2.4.6. Stem cell and other advanced therapy protocols

2.4.7. Clinical Trial Agreements (CTAs) involving Sponsors, Investigators, and MMC, subject to a non-refundable legal and compliance review fee of PHP 134,000

2.4.8. Protocols submitted in parallel to the Single Joint Research Ethics Board (SJREB), per PHREB guideline

2.4.9. Outlines the protocols that were established during the pandemic to ensure safety and health standards.

III. Responsibility

- This section outlines the responsibilities of the MMC IRB members, Secretariat, Administrative Staff, Principal Investigators, and other stakeholders in the initial review and approval of research protocols.

3.1. IRB Members (Reviewers)

- Are responsible for independently completing the appropriate **Protocol Evaluation Forms** (Form 2.7A, 2.7B, or 2.7C) and **Informed Consent Evaluation Form** (Form 2.8), as applicable.
- Must document all comments, evaluations, recommendations, and initial decisions for each assigned protocol.
- Participate in deliberations and ensure that their assessments contribute to the Board's collective decision, which is recorded in the **Minutes of the Meeting**.

3.2. IRB Secretariat and Administrative Staff

- Manage protocol document submissions and assign protocols to the appropriate reviewers.
- Coordinate Full Board or SPARES meetings as applicable.
- Facilitate communications between the IRB and Principal Investigators.
- Maintain accurate and up-to-date electronic protocol files and update the **IRB protocol database** accordingly.
- Ensure that all IRB actions, deliberations, and decisions are recorded and properly filed.

3.3. Primary Reviewers

- Evaluate the scientific and ethical soundness of protocols under their assignment, including expedited reviews.
- Use the same evaluation forms as Full Board reviewers (Forms 2.7A, 2.7B, and 2.8).

- Provide written recommendations to the full board or SPARES group and participate in discussions.

3.4. SPARES Subcommittee Members

- Review minimal risk protocols, including:
  - Prospective observational studies
  - Retrospective reviews
  - Chart reviews
  - Descriptive studies
  - Surveys and questionnaires
- Serve as primary reviewers and contribute to expedited initial review and post-approval monitoring of such studies.

3.5. Secretariat and Admin Staff (for Full Board Review)

- Facilitate the review process by:
  - Scheduling all IRB meetings.
  - Referring protocols to assigned primary reviewers
  - Communicating review outcomes to PIs
  - Maintaining organized documentation in protocol folders and the IRB database

3.6. Primary Reviewers (for Resubmissions)

- Are responsible for reviewing and recommending actions on resubmitted protocols, using prior review feedback and updated documents as references.

3.7. Principal Investigator (PI)

- Must resubmit the revised protocol and **response to IRB comments** within **12 working days** following the release of the **Notification of IRB Decision (Form 2.9)**.
- If no resubmission is received within **6 months** of NOID release, the study is deemed **inactive** and withdrawn from IRB consideration.

3.8. Department Heads/Managers

- Share responsibility with PIs in ensuring the effective implementation of this SOP across relevant departments.

3.9. Clinical Research Center (CRC)

- Facilitates the **contracting process** for clinical trial studies.
- Endorses ethically approved protocols to the **Medical Director**.
- The Medical Director, upon endorsement from the CRC and legal clearance, signs the **Clinical Trial Agreement (CTA)**.
- Processes payment for the **Institutional Fee** before final release of the CTA.

3.10. MMC IRB Participation in SJREB

- MMC IRB **collaborate with the Single Joint Research Ethics Board (SJREB)** for multicenter or national studies.

3.11. MMC IRB Autonomy on SJREB Decisions

- As a **non-DOH hospital REC**, MMC IRB retains the **right to accept or reject** the SJREB recommendation, subject to internal deliberation and institutional policy.

IV. Protocol Submissions

4.1. General Guidelines

4.1.1. The MMC IRB only accepts **complete protocol submissions online**, which must be submitted by the **third week of each month**.

4.1.2. Protocols determined to undergo **Full Board** or **Expedited Review (via SPARES)** will be scheduled for deliberation in the next IRB meeting.

4.1.3. The **Principal Investigator (PI)** has a **7-calendar-day deadline** from the date of screening to complete any missing requirements. If delayed, the **official submission date** will be moved to the date when the final requirement is completed.

4.1.4. The **turnaround time** from submission to final IRB Full Board **Initial Review protocols** and **post approval submissions** is **within 4 weeks**. All protocols undergo both **scientific technical review** and **ethical review**.

4.2. Technical Review Coordination

4.2.1. For Makati Medical Center Protocols

- Technical review must be completed by the **Department Research Committee** before IRB submission.
- The IRB Secretariat provides **standardized technical review criteria** to departments.
- A **Letter of Endorsement** from the Department Research Head or adviser is required.

4.2.2. For Non-Makati Medical Center Protocols

- The MMC IRB conducts both technical and ethical reviews.
- Protocols must follow the **standard IRB format** and include a **Protocol Summary Sheet (Form 2.5)**.
- Documents are screened for completeness using the IRB **Initial Checklist (Form 2.1A)**.
- Institutions must submit a **Memorandum of Agreement (MOA)** with Makati Medical Center.

4.3. Memorandum of Agreement (MOA)

4.3.1. Required MOA Components

Key Elements	Details
1. Parties Involved	Identification of collaborating institutions
2. Title & Introduction	Study title, parties, and rationale
3. Purpose	Objectives of the research
4. Roles & Responsibilities	Defined functions of each party
5. Funding	Budget and payment terms
6. Timeline	Study duration and milestones
7. Intellectual Property	Ownership of data and findings
8. Confidentiality	Data privacy and protection mechanisms
9. Publication	Authorship and dissemination rules
10. Ethical Standards	Research ethics and oversight
11. Protection of Participants	Provision of access to emergency care for SAEs
12. Termination	Grounds and procedure for exit
13. Dispute Resolution	Conflict management framework
14. Anti-Bribery Clause	Compliance with anti-corruption laws
15. Signatories	Names and designations of authorized signers

4.3.2. MOA Screening & Approval Process

1. **Submission**: External institution/researcher submits MOA draft and supporting documents.
2. **Initial Review**: IRB Secretariat checks completeness and forwards to the Legal Department.
3. **Legal Review**: Legal unit ensures alignment with institutional policy and national laws.
4. **Document Finalization**: Two signed hard copies prepared by PI/study team and submitted to the IRB.
5. **Senior Approval**: IRB submits MOA for final approval by the Medical Director.
6. **Signing**: Authorized parties execute the MOA.
7. **Record Keeping**: A physical copy is stored securely in the IRB archive, and a digital version is filed electronically.

4.4. Protocol Submission Package

The protocol submission package must include the following:

Document	Description
1. Letter of Intent	With itemized list of documents submitted, addressed to the IRB Chair
2. CVs & GCP Certificates	Updated CV and GCP training (renewed every 3 years) for PI and Co-Investigators
3. FDA Approval (if applicable)	For trials involving products intended for the Philippine market (FDA Circular 2012-007)
4. Study Protocol	Complete document with rationale, design, inclusion/exclusion criteria, and methodology
5. Informed Consent Forms	In English, Filipino, or other languages (as needed), following IRB consent guidelines
6. Assent Forms	For studies involving minors or vulnerable groups
7. Case Report/Data Collection Forms	For capturing research data
8. Participant Materials	Diary cards, recruitment flyers, posters, etc.
9. Study Budget	Comprehensive budget or financial breakdown
10. Application Forms	Form 2.1A (Application), Form 2.5 (Summary), Form 2.7A/B (Evaluation), Gantt & Flow Charts

11. Investigator's Brochure	For drug/device trials; printed references for non-industry protocols
12. Protocol Files	Electronic copies submitted via official IRB email in the 3rd week of the month, including PowerPoint summary, informed consent, CRFs, literature review (if trainee-led), and other attachments
13. Memorandum of Agreement	For offsite research protocols under MMC-IRB Oversight.

V. Protocol Review Fee

V.1. Standard Review Fees

The following fees apply to research protocols submitted for initial review by the Makati Medical Center Institutional Review Board (MMC IRB):

Type of Protocol	Review Fee
Sponsor-Initiated Protocols	PHP 67,200.00 *(net of withholding tax)*
Investigator-Initiated Protocols	PHP 33,600.00 *(net of withholding tax)*

- Payment should be made payable to "Makati Medical Center".
- The review fee must be settled prior to the release of the Certificate of IRB Approval.

V.2. Payment Arrangements and Alternatives

5.2.1. If payment cannot be made before approval, the Principal Investigator (PI) may submit a Promissory Note as an interim requirement. However, the full payment must be settled within four (4) weeks after the release of the Certificate of IRB Approval.

5.2.2. Wire Transfer Option:

a. The Investigator or Study Team member must email the wire transfer details to the IRB Secretariat as part of the initial submission.
b. The IRB Secretariat confirms payment with the Finance Department.
c. Once verified, the printed wire transfer confirmation must be presented to MMC Cashier 3 (Ground Floor, MMC Tower 1).
d. The payment must be credited to IRB Cost Code 6508000.

e. The Official Receipt should clearly indicate "IRB Review Fee" under the particulars.
f. A copy of the receipt is submitted to the IRB Secretariat and provided to the Investigator.

5.3. Non-Refundable Policy

5.3.1. The review fee is non-refundable and non-transferable once the review process has commenced.

5.3.2. If a trainee-initiated protocol is intended for publication by an external sponsor or pharmaceutical company, the full applicable IRB review fee shall be charged.

5.4. Protocol Code Assignment

5.4.1. Upon verifying a complete submission, the IRB Secretariat assigns a unique protocol code. This code is assigned chronologically based on the submission date, which includes the month and year it was submitted. This will now proceed to:

a. Entered into the IRB database, and
b. Communicated with the Principal Investigator via email.

5.4.2. The issuance of this code marks the official start of the IRB turnaround period, which is four (4) weeks from complete submission to issuance of the Notice of IRB Decision.

VI. Secretariat files the protocol.

VI.1. Put the original copies in an electronic protocol folder.

VI.1.1. Rename the folder file using the MMCIRB Code and the last name of the Principal Investigator.

VI.1.2. **Process Flow Map:**

NO	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Obtain the initial protocol package submitted online for review and verify the completeness of the document requirements, including the IRB Application **Form (Form 2.1A)** signed by the Principal Investigator and the Protocol Summary sheet **(Form 2.5)**. *For investigator-initiated protocols, the research committee of each department must ensure that the technical reviewer	IRB Secretariat	1 working day

	has signed the endorsement provided by the department or unit.		
2	Upon verifying a complete submission, the IRB Secretariat assigns a unique protocol code. This code is assigned chronologically based on the submission date, which includes the month and year it was submitted. This will now proceed to: a. Entered into the IRB database, and b. Communicated with the Principal Investigator via email.	IRB Secretariat	1 working day
3	Acknowledge receipt of the complete documents provided by acknowledging an email the person submitting the package. This will commence the turn-around time of review and approval which is 4 weeks from the time of complete submission to the notice of decision.	IRB Admin Staff	1 working day
4	File the original package in a properly coded electronic Protocol File folder.	IRB Secretariat	1 working day

VII. Protocol Screening

7.1. Screening Process

7.1.1. Upon submission of a complete protocol package, the IRB Secretariat provides the Type of Review Form (Form 2.6) to the Member-Secretary for initial classification.

7.2. Criteria for Review Classification

A. Exempted from Review (EX)

Protocols may be **exempt from IRB review** if they pose less than minimal risk and fall under the following categories:

EX	EXEMPTION CRITERIA
1	Study that does not involve human participants nor identifiable

	tissue, biological samples and data
2	Study design is meta-analysis and/or systematic with non-identifiable data
3	Case Report
4	Study with less than minimal risk or harm
5	Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests

Note: *The PI must submit a formal request for exemption with a justification letter and protocol copy. The Member-Secretary evaluates, and the IRB Chair decides. If exempted, a* ***Letter of Exemption*** *is issued.*

B. Expedited Review (ISER) – *Reviewed by SPARES*

ISER	EXPEDITED REVIEW (SPARES)
1	Protocols of a non-confidential nature (not of a private character, e.g. relate to sexual preference etc., or not about a sensitive issue that may cause social stigma), not likely to harm the status or interests of the study participants and not likely to offend the sensibilities nor cause psychological stress of the people involved.
2	Protocols not involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to participate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent).
3	Protocols that involve collection of anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non- threatening manner).

4	Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis

C. Full Board Review (ISFB)

ISFB	FULL BOARD REVIEW
1	Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3)
2	Phase 4 intervention research involving drugs, biologics or device
3	Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc., or about sensitive issues that may cause social stigma) that may cause psychological, legal, economic and other social harm
4	Protocols involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to participate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent) that require additional protection from the IRB during review
5	Protocols that involve collection of identifiable biological specimens for research

7.3. Review Type Determination and Reviewer Assignment

7.3.1. The Member-Secretary evaluates the protocol using Form 2.6 and recommends the type of review (Exempted, Expedited, or Full Board).

7.3.2. For protocols requiring review, the Member-Secretary recommends the assignment of primary reviewers based on the protocol's subject matter and the reviewers' expertise.

7.3.3. Review assignments consider diversity:

- Medical/scientific reviewers evaluate the protocol's methodology and ethical soundness.
- Non-medical or lay members focus on participant rights, especially the Informed Consent Form.

- Nurses/pharmacists/paramedical members may also review the consent form.
- Assignments aim to include a balance of experienced and newer members.

7.3.4. The Member-Secretary nominates at least two reviewers (one medical/scientific and one non-medical/lay) using Form 2.6.

7.3.5. An independent consultant may be invited if additional expertise is required for technical or ethical evaluation.

7.3.6. The IRB Chair approves the recommended reviewers.

7.3.7. The IRB Secretariat logs the assigned reviewers in the IRB database and stores Form 2.6 in the electronic protocol file.

7.3.8. The Secretariat prepares a review package containing:

- The protocol documents
- Protocol Evaluation Forms (Forms 2.7A and 2.7B)
- Informed Consent Evaluation Form (Form 2.8)

7.3.9. The complete review package is electronically distributed to the assigned primary reviewers for evaluation.

VIII. Protocol Evaluation

8.1. Roles and Responsibilities of Primary Reviewers

Primary reviewers are assigned to assess each submitted protocol using the following standard forms:

- **Protocol Evaluation Forms**: Form 2.7A (Protocol Information Form), 2.7B (Evaluation Form for Initial Submission), and 2.7C (Evaluation Form for Resubmission)
- **Informed Consent Evaluation Form**: Form 2.8

8.1.1. General Review Areas

- Review the study protocol for scientific soundness and ethical considerations.
- Ensure that the CVs of investigators demonstrate appropriate qualifications and GCP certification (if applicable).
- Assess site readiness and facilities for protocol implementation.
- Verify declaration of potential conflicts of interest.
- Recommend physician oversight for non-physician PIs, if necessary.
- Confirm that department/unit technical reviews have been completed (Form 2.7B for trainees).

8.1.2. Review of Vulnerable Populations

- Check **Assent Forms** and verify that procedures for obtaining assent are appropriate and clearly explained for minors or other vulnerable participants, per PHREB guidelines.

8.1.3. Scientific and Ethical Review Guidelines

Primary reviewers evaluate whether:

- The protocol demonstrates **scientific validity**, with complete and logically structured sections.
- **Risk-benefit ratio** is acceptable and all possible risks are minimized.
- **Participant selection** is equitable and justifiable.
- Recruitment is voluntary, non-coercive, and free from undue influence.
- Participant vulnerability is addressed
- The **Informed Consent Form** is:
    - Easy to understand
    - Properly translated to the local dialect (if applicable)
    - Free from coercive or misleading language
    - Clear on the recruitment process as well as who obtains consent and how it is obtained

8.1.4. Privacy, Confidentiality, and Safety Provisions

- Provisions for **data protection**, confidentiality, and participant safety monitoring are in place.
- The study outlines **medical/psychosocial support**, **compensation** for injuries, and **reimbursement** for expenses.
- **Contact information** of investigators is included in consent materials.

8.1.5. Use of Biological Materials

- There is clear justification for the collection and use of biological specimens.
- Future use of specimens requires a **separate consent form**.

8.1.6. Community-Based Studies

Assess whether:

- Local institutions and researchers are involved.
- The study contributes to **capacity building**.
- Results will be **shared with the community**.
- **Community consent and consultation** were secured, where culturally required.
- Cultural sensitivity and local benefits are adequately addressed.

8.1.7. External Sponsor Responsibilities

- Confirm the sponsor's **commitment to post-trial care**, if applicable.
- Financial disclosures and sponsor contributions are transparent.
- Risks to specific ethnic or vulnerable groups are considered in dissemination.

8.2. Evaluation Tools

8.2.1. Protocol Evaluation Form (Form 2.7B/2.7C)

Reviewers assess:

- Study title and objectives
- Literature review and scientific rationale
- Study design, sampling, statistical methods
- Investigator qualifications
- Methodology, safety monitoring, and data management
- Informed consent process and assent (if applicable)
- Compensation and community considerations
- Risk-benefit assessment, conflict of interest, and confidentiality

8.2.2. Informed Consent Evaluation Form (Form 2.8)

Reviewers check for:

- Full disclosure of information
- Clear explanation of risks and benefits
- Voluntary participation/Recruitment process (How, Who, When and Where will the informed consent process will take place)
- Confidentiality protections
- Proper consent signatures
- Indemnity/insurance information

8.3. Review Process Flow

8.3.1. **Completed forms** are signed and submitted to the Secretariat with the reviewed protocol.

8.3.2. **If a primary reviewer does not submit their assessment within three (3) working days**, the protocol is forwarded to the IRB Chair for immediate review to prevent delays.

8.3.3. The Secretariat includes the protocol in the agenda of the next Full Board or SPARES meeting.

8.3.4. Reviewers discuss and finalize recommendations during the assigned meeting. If **revisions** are required:

- The PI is informed and asked to **resubmit revised documents**.
- For expedited/SPARES protocols, **results are communicated directly**, and revisions are reviewed off-meeting.

8.3.5. **Approved expedited/SPARES protocols** are reported during the next Full Board meeting for documentation.

8.3.6. If no resubmission is received **within 6 months**, the protocol is considered **inactive** and archived. The database is updated accordingly.

8.4. Approval and Documentation

8.4.1. Upon approval:

- An **Approval Letter (Form 2.10)** is electronically signed by the IRB Chair and emailed to the PI.
- For protocols requiring Informed Consent, an **IRB Stamp of Approval** is affixed to approved consent forms before distribution to participants.
- A copy of the signed approval letter is saved in the protocol file.

8.4.2. The **IRB database is updated** to reflect the decision.

8.5. **Process Flow Map:**

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Evaluate the scientific/ technical and ethical aspect of the protocol	Primary Reviewers	3 working days
2	Fill out the Protocol Evaluation Forms **(2.7B, 2.7C and 2.8)** during review of the study protocol and related documents.	Primary Reviewers	
3	Submit accomplished Study Evaluation Forms **(2.7B, 2.7C and 2.8)** to the Secretariat	Primary Reviewers	
4	Check forms for completeness and file in the electronic protocol folder.	IRB Secretariat	1 working day
6	Review the protocol either during the full board or SPARES review meeting and decide	Primary Reviewers/ Members	1 working day

7	Communicate the decision of the reviewers/ board to the principal investigator **(Form 2.9)**	IRB Admin Staff	1 working day
8	Prepare an Approval letter **(Form 2.10**	IRB Secretariat	1 working day
9	File copies of Approval Letter in the electronic protocol folder	IRB Secretariat	1 working day

IX. Full Board Review

9.1. IRB Admin Staff

9.1.1. Receives the Application Form for Protocol Review (Form 2.1A/B/C) submitted by the Principal Investigator including the protocol package.

9.1.2. Sends an acknowledgment email to the Principal Investigator upon receipt of the protocol for review.

9.2. IRB Secretariat

9.2.1. Checks forms for completeness and files them in the electronic protocol folder.

X. Member Secretary / Chair

10.1. Determines if the protocol qualifies for a full board review (Form 2.6) based on the criteria.

10.1.1. Selects primary reviewers with appropriate qualifications (a clinician/scientist with expertise related to the protocol and a non-medical person to review the consent form). An independent consultant may be invited to provide an expert opinion.

XI. Review Proper

XI.1. The Secretariat sends the protocol files, together with the assessment forms (Forms 2.7A, 2.7B, and 2.8), to the assigned primary reviewers or independent consultants for review. The Protocol files are accessible to all board members, who can request access to the protocol and other supporting documents through soft copies.

11.1.1. Primary reviewers are informed of the due date for submission of the review checklists and protocol back to the Secretariat. Turn-around time: 3 working days.

11.1.2. Protocol review is conducted as described in Section 2.2 “Protocol Evaluation.”

11.1.3. Primary reviewers indicate the date and affix their signatures in the decision forms (Form 2.7B and 2.8).

11.1.4. Completed forms are submitted to the Secretariat together with the protocol documents. Only completely filled out forms are accepted.

11.1.5. If primary reviewers cannot attend the scheduled full board review, their accomplished forms with comments and recommendations must be returned beforehand. The Chair or Member Secretary may present on their behalf.

XII. Full Board Meeting

12.1. The protocol is scheduled for presentation, discussion, and decision during the next full board meeting.

12.2. Schedule

12.2.1. Regular MMC IRB meetings are conducted every third Tuesday of the month, from 9:00 AM to 1:00 or 2:00 PM, depending on the volume of documents.

12.2.2. A special meeting may be held at the Chair's discretion.

12.2.3. One week's notice is given to MMC IRB members, along with the meeting agenda.

XIII. Attendance and Quorum

13.1 Only MMC IRB members and the IRB Secretariat may attend the meeting, unless otherwise specified.

13.2 The Principal Investigator (PI), a designated representative, or an independent consultant/expert reviewer may be invited to join the meeting during the specific agenda item where their protocol is under review but are removed during discussion and voting.

13.3 For protocols from non-Makati Medical Center institutions, the IRB may solicit comments or seek approval from independent consultants to provide additional expertise as needed.

13.4 Prior to the start of the meeting and protocol review, the Chair ensures that quorum is met and verifies any conflicts of interest among members.

13.5 The meeting will be suspended or adjourned early if quorum is no longer met during the session.

13.6 Meeting Proper:

13.6.1. A primary reviewer presents the protocol summary and highlights key assessments, including scientific merit, ethical considerations, and informed consent.

13.6.2. The Principal Investigator is invited during the presentation of their protocol to respond to questions or clarify any issues raised by reviewers but are removed during any period of discussion or voting.

13.6.3. The Chair facilitates the discussion and summarizes key concerns, if any.

13.6.4. A 5 to 10-minute break may be declared by the Chair to preserve quorum.

13.6.5. Members are discouraged from leaving during reviews to maintain quorum throughout the discussion.

13.6.6. Discussions are divided into two components:

- Part 1: Technical and Ethical Issues
- Part 2: Informed Consent Review

13.6.7. Decision categories for both the protocol and informed consent form include:

- Approved
- Minor Revision
- Major Revision
- Disapproved
- Pending Decision

13.6.8. Voting Procedure:

- The Chair calls for a show of hands.
- The final decision reflects the majority vote.
- Votes are recorded as: For, Against, or Abstain.

13.6.9 The Secretariat's minute taker records the decision using the appropriate section of the assessment form (e.g., Form 2.7B).

13.6.10 All key comments, discussion points, and reasons for decision or disapproval are included in the meeting minutes.

13.6.11 For approved protocols, the MMC IRB sets the frequency for continuing review.

13.7 Post-Meeting Actions

13.7.1 The IRB Admin Staff sends an Action/Approval Letter (Form 2.10) to the Principal Investigator, which includes:

- A list of approved documents with version numbers and dates
- Frequency of continuing review
- Investigator responsibilities

13.7.2 If the protocol is disapproved, a written notification (Form 2.9) is issued with specific reasons for disapproval.

13.7.3 If the Principal Investigator wishes to appeal the decision, a formal written request may be submitted to the MMC IRB.

XIV. For Resubmission

14.1 If the IRB decision requires revision and resubmission of any document, the Secretariat issues a Notice of Decision (Form 2.9) through a formal letter to the Principal Investigator, specifying the required modifications. Once the notice is sent, the turnaround time is paused and will resume upon receipt of the resubmission.

14.2 The Principal Investigator must resubmit the revised documents using Form 2.4 within twelve (12) business days from the date of the Notice of Decision (Form 2.9).

- If no resubmission is received within six (6) months from the issuance of the Notice of Decision, the study is considered inactive and archived.

14.3 Resubmitted protocols are returned to the original primary reviewers by the Secretariat for re-evaluation.

- Reviewers assess only the specific sections that required revision.
- If satisfactorily addressed, the primary reviewers recommend approval.
- If required, the resubmission is included in the next full board meeting for further discussion and final decision. Major modification decisions will be presented directly to the Full Board for discussion and deliberation.

14.4 The Principal Investigator is notified of the IRB's decision via an updated Notice of Decision and Letter of Approval, sent by the IRB Admin Staff.

14.5 For sponsored protocols, the Clinical Trial Agreement is processed by the Clinical Research Center in coordination with the IRB.

14.6 All relevant dates—including IRB decision, document signing by the Chair, and communication to the Principal Investigator—are recorded and updated in the IRB database for documentation and tracking.

14.7. **Process Flow Map:**

NO	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive the complete submitted documents (with **Form 2.2, or 2.4**) and forwards to Member-Secretary and Chair	IRB Admin Staff/ Secretariat	1 working day

2	Determine that the protocol qualifies for Full Board review **(Form 2.6)** and assign reviewers	Member-Secretary Chair	1 working day 1 working day
3	Review the protocol documents, accomplish the assessment forms **(Form 2.7A, 2.7B and 2.8)** and submit the decision/ recommendation to the Secretariat	Primary Reviewers	3 working days
4	Include the protocol in the meeting agenda **(Form 4.1)** for discussion to arrive at a decision through full board	Secretariat/ Members	1 working day
5	Communicate board decision to the principal investigator **(Form 2.9)**	IRB Admin Staff	1 working day
6	If modifications are required, revise the protocol or related document and resubmit to the IRB **(Form 2.4)**	Principal Investigator	
7	Check and review revisions and refer to full board for decision	Primary Reviewers	1 working day
8	After board approval, prepare the Approval Letter **(Form 2.10)** to be electronically signed by the Chair and sent to the Principal Investigator	Secretariat	1 working day

XV. Subcommittee Panels for Minimal Risk Research Protocols (SPARES) Review

The Subcommittee Panels for the Review of Minimal Risk Research Protocols, collectively referred to as SPARES, are established to facilitate the timely and thorough evaluation of protocols classified as

minimal risk. This process allows for an efficient expedited review while maintaining compliance with ethical and scientific standards.

The expedited review process through the Subcommittee Panels for Minimal Risk Research Protocols (SPARES) is used for studies that involve minimal risk to participants. This section outlines the step-by-step responsibilities of the IRB staff and members during this process, ensuring an efficient, ethical, and scientifically sound review.

A. Guidelines:

B. Submission and Acknowledgment

15.1. IRB Secretariat Responsibilities

15.1.1. Receive online applications and required documents (Form 2.1A/B/C) from the Principal Investigator (PI).

15.1.2. Send an acknowledgment email confirming receipt of the protocol.

15.1.3. Screen submitted documents using the designated checklists (Forms 2.4).

15.1.4 Send a follow-up email confirming that the submission has passed the initial screening.

C. Review Assignment and Coordination

15.2. Member-Secretary / Chair Responsibilities

15.2.1. The Member-Secretary recommends the assignment of protocols to SPARES based on the criteria of 2.6 (Type of Review Form). The IRB Chair reviews and approves the recommendations.

- Prospective studies with minimal risk, typically initiated by trainees
- All protocols that meet criteria for Expedited Review
- Retrospective chart reviews
- Descriptive studies, including simple surveys or questionnaires
- Any other research protocols assessed to pose minimal risk to human subject

15.2.2. The Member Secretary recommends the assignment of SPARES protocols to at least two qualified reviewers. The IRB Chair reviews and approves the recommendations.

- A one medical member will evaluate the scientific and technical aspects of the protocol.
- A non-medical reviewer will evaluate the informed consent form.

*In cases requiring specialized knowledge, an independent consultant may be invited to assist as determined by the Chair.

15.3. Reviewers

Protocol Distribution

15.3.1. The Secretariat sends the study documents and assessment forms (Forms 2.7A, 2.7B, and 2.8) to the assigned reviewers.

15.3.2. An itemized cover letter includes a list of submissions and the date from the Principal Investigator.

D. Review and Deliberation

15.4. SPARES Review

15.4.1. Reviewers conduct independent assessments, following the standards in Section IX. "Protocol Evaluation."

15.4.2. The IRB Secretariat coordinates with the assigned SPARES Subcommittee Chair and schedules the review meeting once a month—preferably during the 4th week or 1st week of the month.

15.4.3. Each assigned SPARES reviewer is given three (3) working days to complete their review before the scheduled meeting. The assigned SPARES members meet to discuss and finalize a decision.

15.4.4. The Principal Investigator (PI) may be invited to attend the meeting to clarify specific issues raised during the review but are removed during discussion and voting.

E. Decision-Making and Communication

15.5. If Approved (Protocol is cleared for implementation).

15.5.1. The Secretariat prepares an Action/Approval Letter (Form 2.10) listing the approved documents, their version numbers, and dates.

15.5.2. The IRB Admin Staff sends the approval letter to the PI.

15.5.3. The letter also outlines the frequency of continuing review and the responsibilities of the PI.

15.6. If Disapproved

15.6.1. The SPARES recommendation is presented to the Full Board for final decision.

15.6.2. The Admin Staff communicates the disapproval and the reason to the PI in writing (Form 2.9).

15.6.3. The PI may appeal the decision through a written Letter of Intent addressed to the MMC IRB Chair.

15.7. If Revisions Are Required

15.7.1. Minor Modification – Requires limited revisions; resubmission will undergo expedited review.

15.7.2. Major revisions will require full board review if issues include, but are not limited to:

- Absence of clinical equipoise
- Flaws in study design or methodology
- Significant vulnerability of participants
- Inadequate risk-benefit analysis
- Critical evaluation concerns

*For Full Board Discussion – Protocol complexity or ethical concerns warrant broader review.

15.7.3. Pending Decision – Additional clarification or data is required prior to rendering a final decision.

15.7.4. The Secretariat issues a Notice of Decision (Form 2.9) detailing required revisions.

15.7.5. The turnaround time is paused until the revised submission is received. The PI must resubmit within 12 business days.

15.7.6. If a resubmission is not received within six months, the protocol will be deemed inactive, and the Principal Investigator must resubmit the Initial Protocol Submission for IRB review.

F. Communication and Documentation

15.8. The IRB Secretariat prepares the Notice of Decision to the Principal Investigator based on the SPARES outcome.

15.8.1. The IRB Administrative Staff will email the finalized Notice of IRB Decision to the Principal Investigator.

15.8.2. All SPARES protocol decisions, including approvals, pending actions, or recommendations for disapproval, are formally reported during the next Full Board meeting for documentation.

15.8.3. If the recommendation is disapproval, the final decision is made only after discussion and deliberation by the Full Board.

15.8.4. The IRB database, tracker, and protocol records are updated accordingly to reflect the SPARES review outcome and all related actions.

G. Documentation and Tracking

15.9. Record-Keeping

15.9.1. All deliberations and decisions are documented in the meeting minutes.

15.9.2. Completed assessment forms are filed with the protocol documents.

15.9.3. The IRB database and tracker are updated with:

- Date of decision
- Date the letter was electronically signed by the Chair
- Date the decision was released to the PI

15.10. Process Flow Map:

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	The IRB Secretariat checks the submitted documents for completeness online and will further screen them. **(Form 2.1A, 2.4 and 2.5)**	IRB Secretariat	1 working day
2	The secretariat will forward the submission to determine the type of review of the member secretary/chair. **(Form 2.6, Form 2.5, Form 2.7A)**	Secretariat	1 working day
3	Determine that the protocol is for expedited review **(Form 2.6)** and assigns reviewers.	Member-Secretary/ Chair	2 working day
4	Distributes the protocols for review and coordinates schedule and facilitates the SPARES meeting **(Form 2.7A, 2.7B, 2.7C and 2.8)**	Secretariat	1 working day
5	Conduct expedited review, attend SPARES meeting and submit the decision to the Secretariat **(Form 2.7B, and/or 2.8)**	SPARES Reviewers	3 working days
6	IRB Secretariat will prepare the decision letter based on the outcomes of the SPARES meeting.	Secretariat	3 working days

7	Communicate the decision for approval or revision to the Principal Investigator **(Form 2.9)**	Admin Staff	1 working day
8	If modifications are required, revise the protocol or related document and resubmit to the IRB **(Form 2.7C)**	Principal Investigator	1 working day
9	*If the protocol is for Approval, Secretariat prepares an Approval Letter to be signed by the Chair, and IRB Admin staff will send it to the Principal Investigator. **(Form 2.10)**.	Secretariat/Admin Staff	1 working day
10	Report results of expedited review to full board	Secretariat	1 working day
11	Keep copies of related documents in the electronic protocol file.	Secretariat	1 working day
12	Update the IRB database accordingly	Secretariat	1 working day

XVI. Review of a Medical Device Protocol

The review of protocols involving medical devices requires a distinct approach, taking into account regulatory risk classification, scientific soundness, and subject safety. The MMC IRB follows specific procedures to determine whether a device study qualifies for expedited or full board review, based on risk level and compliance with ethical and technical standards.

A. Initial Submission and Risk Determination

16.1. The Secretariat receives the submitted documents and checks them for completeness. Upon verification, the protocol is forwarded to the Member-Secretary and Chair using Forms 2.1A, 2.5, 2.7A, and 2.7B.

16.2. The Member-Secretary and Chair review communications from the Principal Investigator (PI) regarding whether the investigational device is classified as Significant Risk (SR) or Non-

Significant Risk (NSR) by regulatory authorities (e.g., FDA) in the sponsor country. The protocol is then assigned for either expedited or full board review depending on the risk classification.

16.3. If the FDA has not yet issued a risk determination, the full IRB must review the sponsor's risk classification. The IRB may modify the sponsor's classification if deemed necessary.

16.4. A device study qualifies for expedited review only if:

- It is exempt from IDE requirements, or
- It has been previously determined to be NSR by the FDA or the IRB, and
- It presents no more than minimal risk to the subject (i.e., risks no greater than those encountered in daily life or during routine exams).

B. Reviewer Assignment and Evaluation Process

16.5. Primary reviewers are assigned based on relevant expertise:

- A bioengineer with experience in the investigational device
- A clinician/medical doctor with related clinical experience
- A non-medical/lay member to review the informed consent

16.6. The Primary Reviewers use the MMC IRB Evaluation forms (Form 2.7A, 2.7B, 2.8, and 2.11). When reviewing a medical device protocol, the reviewer should also consider the following (Device Assessment Form 2.11):

- Proposed investigational plan (use of the device in the study)
- Description of the device/ Product information including handling and storage requirements.
- Copies of all labeling for investigational use
- Reports of prior investigations conducted with the device
- FDA Approval, IDE number
- Risk assessment determination for new investigational device (Significant Risk or Non-Significant Risk) and the rationale
- Choice of comparator and justification (if applicable)
- Summary of the necessary training and the experience needed to use the investigational device.
- Device control, access, and accountability.
- List of additional procedures (example: surgery), medical device, or medication to be used as part of the investigational study.
- Risk-benefit assessment
- Safety and effectiveness/ performance assessments

- Prohibition against promotion or commercialization of, and certain other practices relative to, investigational devices.

C. Review Pathways and Decision-Making

16.7. Expedited Review:

Primary reviewers assess the protocol and render a decision. This decision is reported at the next full board meeting for documentation.

16.8. Full Board Review:

The protocol is discussed during the scheduled meeting. If the IRB determines that the device is SR (contrary to sponsor's NSR classification), the PI and sponsor are notified. In such cases, the sponsor must obtain FDA approval before initiating the study.

D. Revisions and Final Decision

16.9. If revisions are required, the Secretariat communicates the board's recommendations to the PI using Form 2.9.

16.10. Turnaround time is paused upon notification and resumes only once resubmission is received.

16.11. Resubmission must include revised Forms 2.1B, 2.4, 2.7A, and 2.7C. The Secretariat receives the documents and routes them to the original primary reviewers.

16.12. Primary reviewers check the revisions through expedited channel for minor revision or sent to full board for review of major revisions.

16.13. Once approved, the Secretariat prepares the Notice of Decision and Letter of Approval (Form 2.10). The letter is electronically signed by the Chair and sent to the PI. It includes the frequency of continuing review.

E. Documentation and Record-Keeping

16.14. All relevant documents are securely filed in the protocol folder. The protocol tracker and database are updated with the latest entries regarding submission status, decisions, and communications.

16.15. **Process Flow Map:**

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE

1	Determine based on risk assessment if the study protocol will undergo the expedited review of the SPARES subcommittee or full board	Member-Secretary/ Chair	1 working day 1 working day
2	Distributes the protocols for review and coordinates schedule and facilitates the SPARES meeting	Secretariat	1 working day
3	SPARES review the protocols for the month and forward the evaluation forms to the Secretariat	SPARES reviewers	3 working days
4	Conduct of SPARES meeting to decide on the protocols	SPARES reviewers	1 working day
5	Sends Notice of Decision to Principal Investigator and reports decisions on SPARES protocols to the next full board meeting. Updates database and index	IRB Admin Staff/ Secretariat	1 working day

XVII. Review of Resubmission

This section outlines the procedure for the review of revised protocols submitted in response to previous IRB recommendations. It ensures timely reassessment while maintaining the rigor of the review process.

A. Receipt and Initial Processing

17.1. The Secretariat receives the resubmission documents, including the required forms—Form 2.1B, Form 2.7A, and Form 2.7C—and checks for completeness using the List of Requirements for Resubmission (Form 2.4).

17.2. Once the submission is confirmed complete, the turnaround time for approval resumes.

17.3. The Secretariat forwards the documents to the original reviewers for assessment.

17.4. If the protocol is for Full Board review, it is included in the agenda of the next scheduled Full Board meeting; the Principal Investigator is not required to attend unless requested, while the Independent Consultant may be invited if needed.

17.5. Reviewers are given three (3) working days to evaluate the resubmission and submit their completed evaluation forms to the Secretariat.

17.6. During the Full Board meeting, the reviewers and board members deliberate on the resubmission and arrive at a decision, which may be: Approved, Minor Modification, Major Modification, Disapproved, or Pending Decision.

17.7. If the reviewers are not satisfied with the PI's response, the IRB will proceed with deliberation and communicate the decision to the PI accordingly.

17.8. The required resubmission documents include a Letter of Intent, Letter of Endorsement (if applicable), the updated Form 2.7C, and other relevant attachments.

17.9. The Secretariat prepares the signed Notice of IRB Decision (Form 2.9) and the Approval Letter (Form 2.10), if the protocol is approved, and communicates the outcome to the Principal Investigator through the IRB Admin Staff.

17.10. For SPARES reviews, the SPARES Chair electronically signs Form 2.9, which is then noted by the IRB Chair.

17.11. For Full Board and Expedited reviews, the IRB Chair electronically signs the appropriate documents—Form 2.9 and/or Form 2.10.

17.12. The Secretariat files all related resubmission documents in the protocol folder and updates the IRB database and tracker to reflect the final status of the review.

17.13. **Process Flow Map:**

NO	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive the submitted documents (with **Form 2.1, 2.7A, and 2.7C)** check for completeness of the requirements **(Form 2.4)** The secretariat will process the submission, check further, and forward it to the Member-Secretary and IRB Chair.	IRB Admin Staff/Secretariat	1 working day

2	Determine the type of review **(Form 2.6)** for the resubmission according to the decision **(Form 2.9)** made during the previous review.	Member-Secretary/ Chair	1 working day 1 working day
3	Distribute the documents to the originally assigned reviewers.	Secretariat	1 working day
4	Review the resubmission and submit the evaluation form to Secretariat For full Board review, final decision is determined during the full board meeting	IRB Members/ Reviewers	1 working day
5	Prepare the Notice of Decision and provide a signed copy of the Notification of IRB Decision **(Form 2.9)** and Approval Letter **(Form 2.10)** to the principal investigator**.**	Secretariat/IRB Admin Staff	1 working day
6	Keep a copy of the approved protocol in the protocol folder and update the IRB database and tracker.	Secretariat	1 working day

XVIII. Policy on Protocol Review for Compassionate Use of Stem Cell Therapy and Others

18.1. *Submission and Preliminary Processing* - The IRB Admin Staff receives the submitted protocol package, including required forms (Forms 2.1A, 2.5, 2.7A, 2.7B, and 2.8). In addition to these standard documents, the following are also required:

18.1.1. Letter of Intent from the patient.

18.1.2. Medical abstract describing the patient's diagnosis and clinical history.

18.1.3. Endorsement letter from the attending physician or a written statement indicating that no other viable treatment options are available.

18.1.4. Signed Informed Consent Form from the patient.

18.1.5. Minutes of the Cellular Therapeutics Ethics Committee meeting, stating the decision or recommendation for compassionate use.

18.2. *Review Determination and Reviewer Assignment* - Once the submission is deemed complete, the Secretariat forwards the documents to the Member-Secretary and Chair for determination of the appropriate review pathway.

18.2.1. Using Form 2.6, the Member-Secretary recommends the review type and identifies primary reviewers. The Chair approves the recommendation and signs Form 2.6. The Secretariat then distributes the protocol package to the assigned reviewers.

18.3. *Guidelines for Review*

18.3.1. All human cells, tissues, and cellular or tissue-based products (HCT/Ps) must be registered under the Philippine FDA, and therapies may only be administered in FDA-licensed and accredited facilities, as stipulated in FDA Circular No. 2013-0017 and FDA Circular No. 2013-020.

18.3.2. To qualify for compassionate use, the patient must meet the following criteria:

a. 18.3.2.1. A confirmed diagnosis of a likely fatal illness (e.g., COPD, Coronary Artery Disease, Congestive Heart Failure).
b. 18.3.2.2. A written statement from a board-certified physician in the relevant specialty affirming that the disease is incurable, the patient is at end-stage, and other reasonable treatment options have failed or are unavailable.
c. 18.3.2.3. The investigational treatment must be reviewed by an ethics committee as if it were research, and informed consent must be obtained in accordance with national legal requirements and cultural standards.

18.4. *Ethical and Scientific Review Scope* - The IRB is responsible for evaluating the following aspects of the proposed therapy:

18.4.1. Ethical implications of the proposed intervention.

18.4.2. Scientific rationale, study design, and data collection plan for safety and efficacy.

18.4.3. Procedures for documentation and reporting of adverse events.

18.4.4. Informed Consent, which must adhere to universal ethical standards, including:

a. Comprehensive details on potential benefits, risks, costs, withdrawal provisions, monitoring plans, and uncertainties.
b. Safeguards ensuring that consent is voluntary and free from undue influence.
c. Provision of a signed copy of the consent form to the patient.

18.5. *Full Board Review and Communication of Decision*

18.5.1. Upon Chair approval, the Secretariat includes the protocol in the Full Board meeting agenda using Form 4.1.

18.5.2. The Full Board discusses the protocol, with mandatory attendance by a lay member.

18.5.3. The Board renders a decision categorized as: Approved, Major Revisions, Minor Revisions, or Disapproved.

18.5.4. The Secretariat prepares the official Notification of IRB Decision (Form 2.9), which is electronically signed by the Chair.

18.5.5. The IRB Admin Staff communicates the signed decision letter to the Principal Investigator.

18.6. **Process Flow Map:**

NO	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive the complete submitted documents (with **Form 2.1A** and forwards to the Member-Secretary and Chair	IRB Admin Staff/ Secretariat	1 working day
2	Determine the Type of Review as Full Board Review **(Form 2.6)** and assign reviewers	Member-Secretary Chair	1 working day 1 working day
3	Review the protocol documents using the guidelines in reviewing protocols on compassionate use. Submit evaluation to Secretariat	Primary Reviewers	3 working days
4	Include the protocol in the full board meeting agenda **(Form 4.1)** for discussion to arrive at a decision through full board	Secretariat / Members	1 working day
6	Prepare the signed Notice of Decision and communicate board decision to the principal investigator **(Form 2.9)**	Secretariat/ IRB Admin Staff/ Chair	1 working day

XIX. Clinical Trial Agreement

19.1. The IRB Admin Staff receives a copy of the Official Receipt reflecting payment of the institutional fee from the Principal Investigator or Sponsor.

19.2. The institutional fee for a Clinical Trial Agreement (CTA) is Php 134,000.00 (net of withholding tax), payable to "Makati Medical Center." A Statement of Account may be requested from the IRB Secretariat to facilitate payment.

19.3. For cash or check payments, the Investigator or Study Team Member must proceed to MMC Cashier 3, located at the Ground Floor of MMC Tower 1, and instruct the cashier to credit the payment to Institution's Cost Code 6000000. The Official Receipt must indicate "Institutional Fee" under the "Particulars" section. A copy of the receipt must be submitted to the IRB Secretariat as part of the CTA submission requirements.

19.4. For wire transfer payments, the Investigator or Study Team Member must email the wire transfer details to the IRB Secretariat. The Secretariat will coordinate with the Finance Department to confirm the payment. Once confirmed, the Investigator must print the confirmation and present it to MMC Cashier 3, requesting that the payment be credited to Institution's Cost Code 6000000. An Official Receipt will be issued, indicating "Institutional Fee" under particulars.

19.5. A copy of the Official Receipt is then provided by the IRB Admin Staff to the Investigator or Study Team Member for their records.

19.6. The Clinical Research Center (CRC) receives and reviews the draft Clinical Trial Agreement (CTA) submitted by the Sponsor or Contract Research Organization (CRO).

19.7. The CRC coordinates legal review of the CTA and returns the legally reviewed version to the Sponsor or CRO for feedback or revision.

19.8. Upon receipt of the final CTA from the Sponsor or CRO, the CRC obtains pre-approval from both the Finance and Legal Departments.

19.9. After all necessary endorsements, the CRC secures the final approval of the CTA from the Medical Director.

19.10. Once approved, the CRC facilitates the release of the fully executed Clinical Trial Agreement to all parties involved.

19.11. **Process Flow Map:**

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	IRB Admin Staff request statement of account details from the Principal Investigator/Sponsor.	IRB Admin Staff	1 working day
2	IRB Admin Staff Endorses the statement of account details to the finance department for the issuance of an official billing	IRB Admin Staff/ Credit Billing & Collection	3-5 working days

	statement. Once the billing statement is received from Finance, the billing statement account will be provided to the Principal Investigator/Study Team.	Department	
3	The IRB Admin Staff will receive the payment advice from the Principal Investigator/Study Team. It must confirm with finance if the payment was already reflected in the Makati Medical Center bank account.	IRB Admin Staff/ Credit Billing & Collection Department	1 working day
4	Once payment is confirmed, a printed copy of the wire transfer payment and confirmation from Finance must be submitted to the MMC Cashier 3, located on the Ground Floor of MMC Tower 1, for issuance of an Official Receipt. Then, ask the cashier to credit the payment to the Institution's Cost Code 6000000.	IRB Admin Staff/ MMC Cashier	1 working day
5	IRB Admin Staff will give the principal investigator/ study team a copy of the official receipt and file the copies in the IRB cabinets.	IRB Admin Staff	1 working day

XX. Single Joint Research Ethics Board (SJREB) Review

20.1. The Makati Medical Center IRB accepts parallel submissions of protocol documents to both SJREB and MMC IRB. The review process shall adhere to the following references:

20.1.1. *Standard Operating Procedures for the Single Joint Research Ethics Board (SJREB), SOP 2: Joint Review of Initial Submission*; and

20.1.2. *MMC IRB SOP Chapter 2, Section 5: Protocol Submission*.

20.2. A letter of intent to join the SJREB review is submitted by MMC IRB, together with the list of members and their curriculum vitae. The participating institution must identify a qualified representative capable of performing scientific and ethical reviews for the specific type of protocol under evaluation.

20.3. When the sponsor selects MMC as one of the sites for multi-site research, the site representative is invited by SJREB to attend and participate in the joint review meeting.

20.4. All protocols submitted for Single Joint Review undergo preliminary evaluation by the MMC IRB Chair or a designated IRB member. At least two reviewers must participate in the preliminary review. An Independent Consultant may be involved at the discretion of the Chair. The process shall follow the MMC IRB SOP for Initial Protocol Review and Approval (Chapter 2).

20.5. Any site-specific issues identified during the preliminary review must be presented by the IRB Chair or designated representative during the SJREB meeting.

20.6. The MMC IRB Secretariat must be updated on the progress and outcome of the SJREB review. A copy of the SJREB meeting minutes shall be requested from the SJREB Secretariat and filed in the protocol folder.

20.7. The joint review arrangement applies to both initial protocol reviews and renewal submissions. However, MMC IRB retains responsibility for reviewing all post-approval submissions, including protocol amendments, reports, and related communications.

20.8. The MMC IRB accepts the final decision of the SJREB unless there are unresolved or site-specific ethical concerns. In such cases, further deliberation within the MMC IRB may be warranted.

20.9. The conduct of the SJREB review follows a process similar to that of a Full Board Review, including quorum verification, documentation, and decision recording.

20.10. The IRB Secretariat prepares a formal communication to the Principal Investigator, stating the review outcome. The communication is signed by the IRB Chair using the appropriate form (Form 2.9 for notice of decision or Form 2.10 for approval).

20.11. The Secretariat files the complete set of protocol-related documents and updates the IRB database and tracking systems accordingly.

20.12. **Process Flow Map:**

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receives parallel submission of protocol to SJREB and MMC IRB. Checks completeness of protocol package and assigns protocol number in masterlist.	IRB Admin Staff/IRB Secretariat	1 working day

	Files the documents in the active protocol folder and prepares corresponding index and tracker. Uploads the protocol package in the Masterlist.		
2	Provides a letter of intent to SJREB to specify the IRB's interest in participating in the joint review of the submitted protocol.	Secretariat	1 working day
3	Receives invite from SJREB for the joint review of the submitted protocol	IRB Admin Staff	1 working day
4	Secretariat informs the IRB Chair. Distributes protocol package to IRB chair (or designate) and assigned reviewers	Secretariat	1 working day
4	Conduct a preliminary review of the protocol prior to SJREB review meeting and appoints representative to SJREB meeting.	IRB Chair (or designated member) and SPARES committee assigned for the month	3 working days
5	Presents all issues identified during the SJREB Meeting	IRB Chair or the designated representative	1 working day
6	Receive communications (e.g., status of the review, approval letter, etc.) from SJREB	IRB Admin Staff	1 working day

7	Review of protocol with decision from SJREB and report during the next IRB Full Board meeting	IRB Chair (or designated member) and reviewers assigned for the month	1 working day
8	Communicate the decision of the review to the Principal Investigator	SJREB Secretariat	1 working day
9	Keep copies of the protocol and protocol-related documents in the protocol file including SJREB meeting minutes	Secretariat	1 working day
10	Update the IRB masterlist and protocol tracker	Secretariat	1 working day

XXI. Submission, Review and Approval of Research Protocol and Post Approval Documents during Pandemic Emergency

XXI.1. **Scope:** This section outlines the protocols that were established during the pandemic to ensure safety and health standards.

XXI.2. The IRB Admin Staff verifies the completeness of the submitted online documents by comparing them to the requirement checklist within one working day of receipt. Once the documents are confirmed as complete, an acknowledgment receipt is sent to the sender. The turnaround time (TAT) for review and approval begins from this point.

XXI.3. The Secretariat assigns a permanent MMC IRB code to the submission package. The complete submission is recorded in the electronic logbook and the electronic masterlist database. An electronic folder is created in the MMC-IRB OneDrive system to store all related documents.

XXI.4. The IRB Secretariat sends the complete protocol package to the Member-Secretary via email, requesting the recommendation for the appropriate type of review and assignment of primary reviewers.

XXI.5. The Member-Secretary determines and recommends the type of review as based on Section 7 “Criteria for Review Classification” defined criteria and assigns the primary reviewers accordingly.

XXI.6. The Secretariat forwards the protocol and Member-Secretary's recommendations to the IRB Chair for approval. The IRB Chair is expected to provide feedback, suggestions, or corrections within one (1) working day of receipt.

XXI.7. The IRB Secretariat will send the forms, protocol, and necessary supporting documents to the assigned reviewers for their review.

XXI.8. The reviewers will assess the scientific and technical aspects of the protocol, as well as the ethical considerations related to informed consent. This evaluation period will last from one (1) to seven (7) days, depending on the flexibility of the review process.

XXI.9. Once approved, the Secretariat includes the protocol in the agenda of the next appropriate review meeting—either a Full Board Review or SPARES Review—based on the review type determined.

XXI.10. The IRB Admin Staff schedules an online meeting by reserving a Zoom slot at least one (1) week before the intended IRB meeting date—every third Tuesday of the month for Full Board Reviews, or as scheduled by the SPARES Chair for expedited reviews.

XXI.11. The IRB Admin Staff disseminates the Zoom meeting details, including passcodes, to all IRB members.

XXI.12. Within one (1) working day after the Zoom meeting is scheduled, the Secretariat initiates a quorum check by posting an availability inquiry in the official MMC-IRB Viber Group.

XXI.13. The IRB Chair, Member-Secretary, and members must respond to the quorum check—either confirming availability or stating their absence—within one (1) working day of receiving the notice. The review of the protocols falls within the

XXI.14. Here are the criteria for evaluating protocols related to pandemics.

XXI.15. **Process Flow Map:**

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Schedules the meeting through ZOOM virtual reservation	IRB Admin Staff	1 working day
2	Sends notice of meeting for a quorum and coordinates meeting details to the Board	IRB Admin Staff	1 working day

4	Confirmation of attendance in the meeting	Chair, Member-Secretary, and IRB Members	1 working day

XXII. Preparation of Meeting Minutes

Process Flow Map:

XXII.1.1. Organize and document the meeting procedures and the items taken up based on the meeting agenda (Form 4.1)

XXII.1.2. Preparation of the draft of live minutes of the meeting (Form 4.2).

XXII.1.3. **Process Flow Map**

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Organize and document the meeting procedures and the items taken up based on the meeting agenda (Form 4.1)	Secretariat	1 working day
2	Preparation of the draft of live minutes of the meeting	Secretariat	1 working day

XXIII. Distribution of Submissions for Review

Process Flow Map:

XXIII.1.1. Secretariat uploads the soft copy of the files for review (initial proposal, SAEs, post approval monitoring).

XXIII.1.2. Secretariat creates a folder in the computer containing the protocols for review.

XXIII.1.3. Secretariat sends the protocols to the designated reviewers in a zip folder.

XXIII.1.4. **Process Flow Map**

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Upload the soft copy of the files for review	Secretariat	1 working day
2	Create a soft copy of folders containing the protocols for review.	Secretariat	1 working day

3	Send the protocols to the designated reviewers in a zip folder.	Secretariat	1 working day

XXIV. Online Full Board Meeting (Before the meeting)

XXIV.1.1. Make a Zoom schedule through the IRB Zoom Account. Send calendar invites schedule of the IRB Full Board/SPARES/Special Meeting.

XXIV.1.2. Secretariat prepares the Agenda of the Meeting (Form 4.1) for the month.

XXIV.1.3. Secretariat prepares the Minutes of the Meeting for the month

XXIV.1.4. Secretariat uploads, prepares, and sends the files that will be distributed to the reviewers.

XXIV.1.5. IRB Admin Staff/Secretariat reminds the IRB Members, Independent Consultants/Expert Reviewers, and Principal Investigators regarding the schedule of the IRB Meeting.

XXIV.1.6. Secretariat reports other matters to the Board

XXIV.1.7. IRB Chair adjourns meeting.

XXIV.1.8. **Process Flow Map**

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Make a Zoom schedule through the IRB Zoom Account. Send calendar invites	IRB Admin Staff	1 working day
2	Prepare the Meeting Agenda for the month.	Secretariat	1 working day
3	Prepare the Minutes of the meeting.	Secretariat	1 working day
4	Upload, prepare, and send the soft copy of the files that will be distributed to the reviewers.	Secretariat	1 working day
5	Remind the IRB Members, Independent Consultants/Experts Reviewers, and the Principal Investigators regarding the schedule of the IRB Meeting.	IRB Admin Staff/ Secretariat	1 working day

XXV. Online Review Meeting (after the meeting)

XXV.1. Checks completeness of accomplished evaluation forms and stores meeting materials in the cloud before deleting used files in the computer/laptop.

XXV.2. Secretariat collects the ZOOM cloud recording of the meeting.

XXV.3. Secretariat completes the minutes of the meeting to be sent to the Member- Secretary for review.

XXV.4. IRB Chair edits the minutes of the meeting and approves it.

XXV.5. Secretariat archives the approved minutes of the meeting, agenda of the meeting, and accomplished evaluation forms of the reviewers

XXV.6. Secretariat distributes the Notification of IRB Decision (Initial proposal, SAEs, Post approval monitoring) to the designated principal investigators.

XXV.7. **Process Flow Map**

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Collection of accomplished assessment forms from the reviewers.	Secretariat	1 working day
2	Collection of meeting recording from the zoom app	IRB Admin Staff/Secretariat	1 working day
3	Polishing of Minutes of the Meeting	Secretariat	1 working day
4	Review, correction and approval of Minutes of the Meeting	Member-Secretary/IRB Chair	1 working day 1 working day
5	Filing of Minutes of the Meeting, Agenda of the Meeting, and Accomplished evaluation forms.	Secretariat	1 working day
6	Distribution of Notification of IRB Decision to the principal investigators	IRB Admin Staff	1 working day

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

Signatories:

Author (s)	**Rocelle F. Surat, CLSSYB** IRB Assistant Institutional Review Board **Joshua Jaime P. Nario, DLGHCO, MA, RN** IRB Member-Secretary Institutional Review Board
Reviewers	**Carolyn A. Butler, MD** Institutional Review Board

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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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

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:

Author (s)	Carolyn A. Butler, M.D. IRB Chairman Institutional Review Board Mr. Joshua Jaime P. Nario, DLGHCO, MA, RN IRB Member-Secretary Institutional Review Board Rocelle F. Surat, CLSSYB IRB Assistant Institutional Review Board Ann Pauline R. Dela Cruz, CLSSYB

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

MAKATI MEDICAL CENTER

Departmental General Operating Procedures

Chapter IV. Documentation and Archiving	Document Code: IRB-GOP-DAA-004	Rev. Code : 09
	Effective Date: December 30, 2025	Page 1 of 17

Issued by: Institutional Review Board	New ☑	Supersedes: IRB-SOP-1120-DAA-004-08

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.

Signatories:

Author (s)	Carolyn A. Butler, M.D. IRB Chairman Institutional Review Board Mr. Joshua Jaime P. Nario, MA, RN, CLDP IRB Member-Secretary Institutional Review Board Rocelle F. Surat, CLSSYB IRB Assistant Institutional Review Board

Reviewers	Full name: Department/ Division: ***(may add additional reviewer as necessary)*** Full name: Department/ Division:

MAKATI MEDICAL CENTER

Departmental General Operating Procedures

Chapter V. Writing and Revising Standard Operating Procedures (SOPs)	Document Code: IRB-GOP-WRS-005	Rev. Code : 09
	Effective Date: December 09, 2025	Page 1 of 9

Issued by: Institutional Review Board	New ☑	Supersedes: IRB-SOP-1120-WRS-005-04

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 establish the process for writing and revising Standard Operating Procedures (SOPs) utilized by the Makati Medical Center Institutional Review Board (MMC IRB).

II. Scope:

2.1. This SOP outlines the procedures for preparing, approving, and distributing MMC IRB SOPs.

III. Definition of Terms:

3.1. Standard Operating Procedure (SOP) – A set of written instructions that detail the step-by-step processes to be followed in order to carry out specific tasks or operations consistently and efficiently within an organization.

3.2. Sop document Code – A unique identifier assigned to an SOP document, typically following a standardized format that helps in organizing, locating, and referencing SOPs within a document control system.

3.3. Draft – A preliminary version of a document that is under development and has not yet been finalized, approved, or issued for official use.

3.4. Revision – An updated version of a document that reflects changes, corrections, or improvements made to the original or previous version. Each revision is typically tracked with a version number or date.

3.5. Tracking – The process of monitoring and recording changes, updates, or the status of a document (such as an SOP) to ensure accurate version control and traceability.

3.6. Coding – The process of assigning standardized codes or identifiers to documents (e.g., SOPs) to categorize, manage, and retrieve them efficiently within a system.

3.7. Superseded – Refers to a document that has been replaced by a newer version. A superseded SOP is no longer in effect and should not be used.

3.8. Effectivity Date – The date on which a document (e.g., an SOP) becomes officially active and enforceable for use within the organization.

3.9. SOP Manual – A comprehensive collection or compilation of all SOPs relevant to a particular department, process, or organization, often organized for easy access and reference.

3.10. Outdated SOP – An SOP that is no longer current or valid due to process changes, updates, or replacement by a revised version. It should not be used unless revalidated.

IV. Responsibility:

4.1. The Chair of the MMC Institutional Review Board (IRB) is responsible for appointing a Standard Operating Procedure (SOP) Team tasked with formulating or revising the SOPs of the MMC IRB. The Chair designates the team members, initiates the approval process for the final version of the SOPs, and submits the SOPs to the Medical Director of Makati Medical Center for final approval.

4.2. The SOP Team is an ad hoc committee made up of appointed MMC IRB members, along with invited resource persons. This team is responsible for proposing and developing new SOPs, as well as reviewing and revising existing SOPs as needed. When drafting or editing any SOPs, the team must adhere to the hospital's established procedures, format, and coding system.

4.3. They should also consult with the Secretariat and the Chair to determine if new or revised SOPs are necessary. Once the drafts are completed, the team submits them to the Chair for approval processing. The Secretariat coordinates the writing and revising of SOPs, maintains an up-to-date list of all current SOPs, and ensures that all MMC IRB members have access to the SOPs while working with the latest versions.

4.4. MMC IRB members are responsible for reviewing and approving drafts of new or revised SOPs during full board meetings. They must keep copies of all complete SOPs and perform their duties according to the current SOPs. Finally, the Medical Director of MMC is responsible for the final approval of all SOPs.

V. Writing Standard Operating Procedures

5.1. Guidelines:

No.	ACTIVITY	RESPONSIBILITY
1	Design the format, layout, coding identifier of SOP	SOP Team
2	Write a new SOP and submit to Chair	SOP Team
3	Review and approve new SOP draft in a full board meeting and submit to the Medical Director.	IRB Members/ Chair
4	Approve and sign new SOP	Medical Director
5	File/ distribute approved SOPs	Secretariat

5.1.1. The Standard Operating Procedure (SOP) is introduced with a conventional format, which includes the following essential elements:

5.1.1.1. Title of the document

5.1.1.2. Institutional contact information, including address, telephone numbers, and email address

5.1.1.3. Date of the previous version; if there is no previous version, please indicate "N/A" (Not Applicable

5.1.1.4. Names of the authors and editors responsible for this document

5.1.1.5. Approval information, detailing the approving authorities and applicable offices

5.1.2. SOP Document Code

5.1.2.1. Each SOP chapter is given a code and a title that is self-explanatory and is easily understood. For the Makati Medical Center IRB SOPs, the following format is used: IRB-GOP-XXX-YYY-RR where XXX is a three-letter chapter code. YYY is the three-digit chapter number. RR reflects the revision number.

5.1.3. SOP Header Layout:

5.1.3.1. The layout of a typical SOP uses a header with the following elements:

5.1.3.1.1. Institutional seal or logo
5.1.3.1.2. Name of institution
5.1.3.1.3. SOP identifier
5.1.3.1.4. SOP section
5.1.3.1.5. SOP title
5.1.3.1.6. Effective date
5.1.3.1.7. Page number

5.1.4. SOP is divided into the following sections:

5.1.4.1. SOP Revision Tracker
5.1.4.2. Abbreviation Index
5.1.4.3. Chapters 1 to 6
5.1.4.4. IRB Forms
5.1.4.5. Appendices/Attachments
5.1.4.6. SOP Approval Sheet

5.1.5. Format and layout of each SOP chapter is as follows:

5.1.5.1. Number and version
5.1.5.2. Title
5.1.5.3. Objectives of the SOP
5.1.5.4. Scope which includes description and purpose of the SOP
5.1.5.5. A flowchart when necessary
5.1.5.6. Detailed instructions

5.1.6. SOP Writing, Review and Approval

5.1.6.1. SOP Team makes a draft of the SOP based on the design and format detailed above. SOP Team submits completed draft to the Chair.

5.1.6.2. Completed draft is submitted to Member-Secretary, Vice-Chair and Chair for review.

5.1.6.3. The chair presents the draft for full board review, where IRB members discuss it with the help of IRB Secretariats.

5.1.6.4. The IRB members will require a quorum of favorable votes to recommend the SOP.

5.1.6.4.1. If the decision is to defer, the member secretary will manage the discussion along with the IRB Chair. The members will collaborate to reach a favorable vote.

5.1.6.5. Upon full board approval, the Chair submits the approved draft to the Medical Director for final approval.

5.1.6.6. The IRB secretariat will ensure that comprehensive minutes of the meeting are documented.

5.1.6.7. Makati Medical Center Director approves the SOP by signing in the appropriate section in the cover page.

5.1.6.8. The approved SOPs will be implemented from the date of approval by the Medical Director.

5.1.7. Filing and Distribution of SOP

5.1.7.1. Upon approval from the Medical Director of Makati Medical Center, the Secretariat distributes the Standard Operating Procedures (SOPs) to the members of the Makati Medical Center Institutional Review Board (IRB) via electronic copies.

5.1.7.2. The SOPs are also published on the official MMC IRB website (https://irb.makatimed.net.ph/manuals-of-sop/)

5.1.7.3. Additionally, the Secretariat keeps one signed copy of the complete SOPs for their records.

5.1.8. Revising Standard Operating Procedures (SOPs)

5.1.8.1. SOP is reviewed and revised at least every three years or as necessary when MMC IRB sees fit.

5.1.8.1.1. A revision should be substantial (correction of grammatical errors is not considered substantial;

5.1.8.1.2. A change in the identifier of an SOP is considered substantial).

5.1.8.1.3. When an SOP is difficult to understand or does not cover what it should, a revision may become necessary.

5.1.8.1.4. Major changes, on the other hand, are those that have a substantial effect on procedures, definitions, requirements, and similar considerations.

5.1.8.1.5. Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures.

5.1.9. Process Flow

NO.	ACTIVITY	RESPONSIBILITY
1	Propose to revise an SOP	IRB Member
2	Review, discuss and approve the SOP draft revision in a full board meeting.	IRB Members
3	Approve and sign the SOP revision	IRB Chair and Medical Director
4	File/ distribute the revised SOP	IRB Secretariat
5	Include the revised SOP in the SOPs manual that is currently used	IRB Secretariat
6	Archive the superseded SOP	IRB Secretariat

5.1.10. Revision Proposal

5.1.10.1. When the need for a revision of SOP has been identified and agreed on, a draft will be written by a designated member of the MMC IRB.

5.1.10.2. Any member of the board may propose for the revision of the SOPs.

5.1.10.3. Any proposal for revision must be written and submitted to the board for review, approval, coding, and inclusion into the document.

5.1.10.4. The proposal is discussed and acted upon through full board review.

5.1.10.5. The draft version will be reviewed by the Chair who will submit it to the Medical Director for approval.

5.1.11. Approval and Effectivity

5.1.11.1. The Makati Medical Center Medical Director and Chair of the IRB approve the revised SOP by signing on the appropriate section of the cover page.

5.1.11.2. The approved revised SOP will be effective 14 days upon the approval and signing of the Medical Director.

5.1.12. Revision Tracking and Coding

5.1.12.1. SOP revision number in chronological order as well as date of the revision is reflected on the SOP document code, example IRB-GOP-WRS-005- 01.

5.1.12.2. If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the SOP Revision Tracker on the SOP cover, located in front of the SOP manual.

5.1.13. Distribution of Revised SOP

5.1.13.1. Upon approval of Makati Medical Center Medical Director, the Secretariat distributes the printed revised SOP to Makati Medical Center IRB members, updates the electronic SOP manual, and publishes the SOP through the Hospital website.

5.1.13.2. Secretariat collects the old SOP manuals in exchange of the revised manual.

5.1.13.3. The Secretariat distributes the latest version of the SOP in both printed and electronic formats within 30 days of approval by the Medical Director.

5.1.13.4.

5.1.14. Archive superseded SOP

5.1.14.1. A. Secretariat maintains the originally signed updated SOP manual in the

5.1.14.2. MMC IRB office and retains one copy of the originally signed outdated versions.

5.1.14.3. Superseded SOPs are clearly marked “superseded" with the year of archiving stamped in the cover page.

5.1.14.4. The Secretariat archives the superseded version of the SOP in the historical file maintained by the Makati Medical Center IRB.

5.1.14.5. Outdated SOPs are considered a permanent file.

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

Signatories:

Author (s)	Carolyn A. Butler, M.D. IRB Chairman Institutional Review Board Mr. Joshua Jaime P. Nario, MA, RN, CLDP IRB Member-Secretary Institutional Review Board Rocelle F. Surat, CLSSYB IRB Assistant Institutional Review Board
Reviewers	Full name: Department/ Division: ***(may add additional reviewer as necessary)*** Full name: Department/ Division: