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
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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.

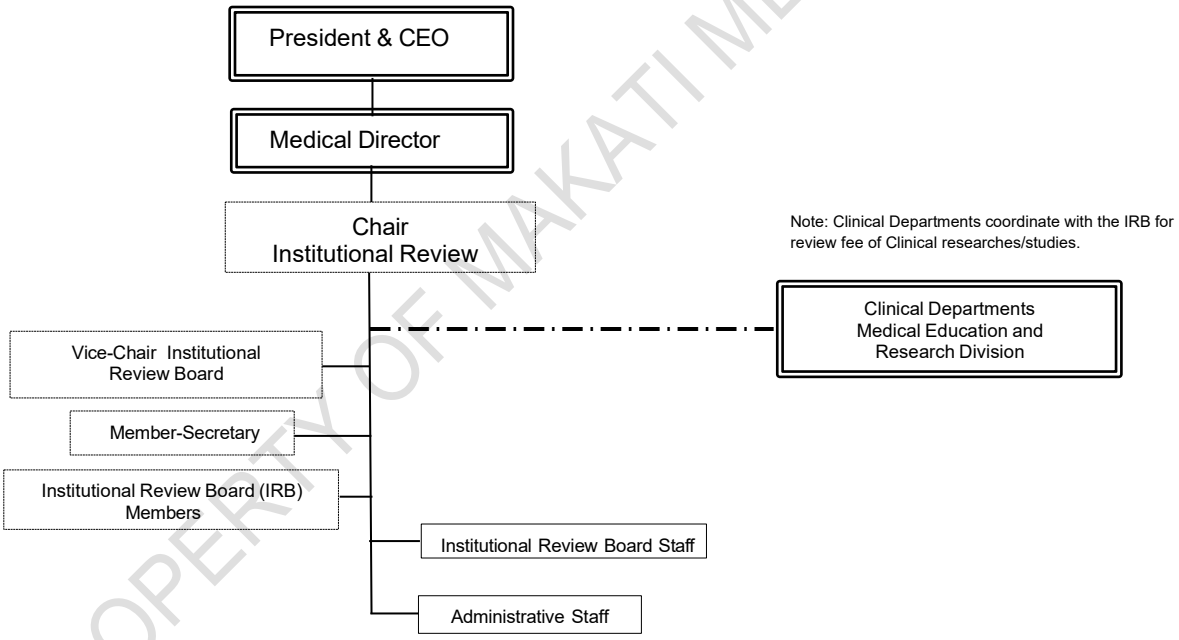
V. Constitution - Organizational Structure

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	