MAKATI MEDICAL CENTER

Departmental General Operating Procedures

Chapter II: Initial Protocol Review and Approval	Document Code: IRB-GOP-IPR-002	Rev. Code : 09
	Effective Date: December 30, 2025	Page 1 of 43

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