APPENDICES:

I. Definition of Terms: A list of terms and their definitions as used in the General Operating Procedures.

Term	Definition
1. Institutional Review Board (IRB)	An independent committee established by Makati Medical Center under the Medical Director to review and oversee research involving human participants.
2. Research Protocol	A detailed plan outlining the background, objectives, methodology, and ethical considerations of a research study.
3. Memorandum of Agreement (MOA)	A formal document detailing cooperative responsibilities between MMC IRB and external entities.
4. Ethical Review	The process of evaluating research protocols to ensure adherence to ethical standards and protection of participant rights.
5. Full Board Review	A comprehensive review of research posing more than minimal risk, conducted by the convened IRB.
6. Expedited Review	A faster review process for minimal-risk studies conducted by designated IRB members.
7. Medical / Scientific Members	Licensed physicians or health professionals with research expertise
8. Non-Medical / Scientific Members	Professionals from health-allied fields (e.g., nursing, pharmacy, paramedical)
9. Independent Consultant	Designated independent consultants are available to provide substitute or advisory support as required.
10. SPARES	Subcommittee Panels for Minimal Risk Research Protocols, composed of regular MMC IRB members.
11. Serious Adverse Event (SAE)	An unexpected medical event during research that results in serious harm or risk to participants.
12. Good Clinical Practice (GCP)	An international standard for designing, conducting, and reporting research involving human subjects.
13. Compassionate Use	Use of a treatment outside a clinical trial in patients with serious or life-threatening conditions when no other effective options are available.
14. Stem Cell Therapy	A procedure that uses stem cells to treat or prevent diseases or conditions.

15. Standard of Care	An intervention generally accepted by medical experts as appropriate and effective.
16. PHREB	Philippine Health Research Ethics Board – the national policymaking body on health research ethics in the Philippines.
17. PHREB Resolution No. 20-001	A 2020 resolution allowing RECs to modify SOPs and conduct online reviews during the COVID-19 pandemic.
18. COVID-19	A viral respiratory disease caused by SARS-CoV-2, with public health implications affecting research and IRB procedures.
19. Exempt from Review	Protocols meeting criteria that exclude them from IRB review (e.g., case reports, QA/QI studies, meta-analyses without identifiers).
20. Principal Investigator	The lead researcher responsible for conducting and overseeing the study at the research site.
21. Protocol Screening	The process of determining the appropriate type of review and assigning protocol reviewers.
22. Designated Staff of Research Team	A delegated administrative staff member allowed to submit or inquire about IRB matters on behalf of the PI.
23. Clinical Research Officer/Assistant	Staff from a Clinical Research Organization tasked with submitting documents and coordinating IRB-related activities.
24. Coding	The assignment of an official MMC IRB code to a new protocol submission.
25. Electronic Log Book	A digital record of all submissions received, including dates, sender names, and receiving staff.
26. Electronic Master List Database	A restricted-access database within MMC's intranet for tracking all approved protocols.
27. Memorandum of Agreement (MOA)	A formal document detailing the cooperative arrangement between the institution and external parties.

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 systemic with identifiable data
3	Case Reports
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

28. Electronic Protocol Folder	A secure cloud-based folder containing all protocol submission files.
29. Official Email	The IRB-dedicated MMC email used for confidential communication and document handling.
30. Type of Review	Classification of review as Full Board, Expedited, or Exempt based on protocol content and risk level.
31. Primary Reviewers	IRB members assigned to conduct initial assessments of a protocol before board presentation.
32. Independent Consultant	An external expert reviewer appointed to assess protocols requiring specialized knowledge.
33. Virtual Meetings	Online IRB meetings conducted via secure platforms such as Zoom.
34. IT Host/IT Staff	MMC personnel responsible for technical setup and security of IRB virtual meetings.
35. Virtual Conference Reservation Application	MMC's internal system for scheduling secure online meetings.
36. Zoom	A cloud-based video conferencing tool used for virtual IRB sessions.
37. Meeting ID / Password	Credentials required to access secure virtual IRB meetings.
38. Visual Aids	Meeting materials such as PowerPoint presentations, protocol agendas, and discussion documents.
39. Quorum	Minimum number of IRB members required to conduct valid board decisions.
40. Conflict of Interest	A situation where a reviewer's personal or professional interest could bias their evaluation.
41. Agenda of the Meeting	The official list of protocol submissions and matters to be discussed during the IRB meeting.
42. Minutes of the Meeting	The official written summary of the IRB's review discussions and decisions.
43. Approved Protocols	Protocols that have passed IRB evaluation and are cleared for implementation.
44. Full Board Review	Review for protocols involving major risks or substantial revisions affecting participant safety.
45. Expedited Review	Streamlined review for protocols with minimal risk and minor changes.

46. Other Matters	Meeting items unrelated to specific protocols, such as training announcements or financial updates.
47. Decision Letters	Official IRB communications to investigators regarding the outcome of the protocol review.
48. A serious adverse event (SAE) or a serious adverse drug reaction (ADR)	ICH-GCP E6 (R3) defines - as any untoward medical occurrence that at any dose results in death is life threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or results in a congenital anomaly or birth defect.
49. Suspected unexpected serious adverse reactions (SUSARs)	are considered off-site submissions. If the Principal Investigator (PI) or Sponsor is required to have a Notification NOID (Notice of the IRB decision) regarding the SUSAR, these are usually submitted as notification reports. They may also be submitted along with the study's Continuing Renewal/ Progress Report as supporting documents.
50. Protocol deviation or violation	is generally an unplanned excursion from the protocol that is not implemented or intended as a systematic change. ● This SOP provides instructions for taking action and maintaining records of various types of protocol deviation or violations: ● It includes investigators who fail to comply with the procedures in the approved protocol or to comply with national/ international guidelines for the conduct of human research. ● It also covers action taken by the IRB related to protocol violation/ deviation reports submitted by the principal investigator related to any event at the site that is not in compliance with the protocol documents previously approved by the IRB. ● Initiation and/or implementation of any non-approved study protocol shall be considered a VIOLATION of the standard operating procedures of the MMC IRB. ● Any ongoing non-registered or non-approved study shall be suspended until the study proponents fully comply with the IRB requirements.

51. Protocol violation

- is any serious noncompliance which may lead to exclusion of patients from eligibility analysis and/or heir discontinuation from the study. It has material consequences such as but not limited to 1) reduces the quality or completeness of the data, 2) makes the informed consent inaccurate, 3) impacts a subject's safety, rights or welfare.
- Examples of protocol violations may include the following:
- Inadequate or delinquent informed consent
- Inclusion/exclusion criteria not met
- Unreported serious adverse events
- 1Improper breaking of the blind
- Use of prohibited medication
- Incorrect or missing tests
- Mishandled samples
- Multiple visits missed or outside permissible windows
- Materially inadequate record keeping
- Intentional deviation from protocol, GCP or regulations by study personnel
- Subject repeated non-compliance with study requirements

52. FOR EXPEDITED REVIEW (WITH MINOR AMENDMENT)

RSER	EXPEDITED REVIEW (SPARES)
Q	• Protocol amendments that have minor modifications and no significant risk to study participants, such as:
1	• Administrative revisions, such as correction of typing errors
2	• Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
3	• The research activity includes only minor changes from previously approved protocol.
4	• Minor protocol amendments that do not change the risk/ benefit assessment

53. FOR FULL BOARD REVIEW (WITH MAJOR AMENDMENT):

Amendments that may potentially alter the risk/benefit ratio of a study are referred for full board review. Protocol amendment

which increases risk to study participants may include, but is not limited to the following:

- a change in study design
- additional treatments or the deletion of treatments
- any change in the inclusion/exclusion criteria
- change in method of drug intake or route of drug intake (e.g. oral changed to intravenous)
- significant change in the number of subjects (increase or decrease in sample size that alters the fundamental characteristics of the study)
- significant decrease or increase in dosage amount

RSFR	FULL BOARD REVIEW
1	Major revisions of the protocol and informed consent after initial review
2	Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/ exclusion criteria, safety issues, etc.)
3	Major amendments that change the risk/ benefit ratio

54. A site visit is an on-site or virtual assessment conducted by the Institutional Review Board (IRB) or its designated representatives to evaluate the conduct of a research study at a specific location. The purpose of a site visit is to ensure that the study is being conducted in compliance with:

- The approved research protocol,
- Institutional Review Board (IRB) requirements,
- Good Clinical Practice (GCP) guidelines, and
- Applicable regulatory and ethical standards.

Criteria for a site visit would include but is not limited to:

- To ensure site is adequately situated, with proper structures for conduct of the study and staffed for the proposed research study
- To ensure Applicable regulatory and ethical standards are being followed by the study team
- To address reports of frequent complaints of participants
- To comply with SJREB and or refractory recommendations

55. A final report	is a comprehensive summary submitted by the principal investigator to the Institutional Review Board (IRB) upon the completion of a research study. It marks the official closure of the study and provides documentation that all research activities, including participant follow-up and data collection, have been concluded.
56. Early study termination or withdrawal	refers to the discontinuation of a research study or a specific research site prior to the planned or IRB-approved completion date
57. Annual Report or Continuing Review	is the periodic re-evaluation of an ongoing research study by the Institutional Review Board (IRB) to ensure continued compliance with ethical standards, regulatory requirements, and IRB-approved protocols. This review is mandated at least once every 12 months (or more frequently, as deemed necessary by the IRB), in accordance with international guidelines such as ICH-GCP and local regulations.
58. Notification	A type of regulatory submission made to notify relevant authorities of changes or updates that occur after the initial approval of a product.
59. CIOMS (Council for International Organizations of Medical Sciences)	is an international, non-governmental organization that collaborates with WHO and other stakeholders to develop guidance on ethics, pharmacovigilance, and health research. In the context of ICH GCP E6(R3), CIOMS is particularly referenced for its standardized formats and procedures in safety reporting, such as the CIOMS I form used for expedited reporting of adverse events.
60. Investigator's Brochure	A compilation of the clinical and nonclinical data on the investigational product(s) that is relevant to the study of the product(s) in human subjects.
61. Development Safety Update Report	is a periodic safety report prepared by the sponsor of a clinical trial to provide an annual summary of safety information about an investigational product under development.
62. Site Closure	refers to the formal conclusion of all trial-related activities at a clinical trial site, following verification that all necessary data have been collected, documented, and reported, and that all regulatory, ethical, and contractual obligations have been met. It typically includes final monitoring visits, reconciliation of investigational products, resolution of data queries, and secure archiving of trial documents.

63. End of Trial	refers to the point at which all trial-related activities are concluded at all sites, typically defined in the protocol, and generally marked by the last visit of the last subject, or the completion of all required data collection and follow-up, whichever occurs later.
64. Pregnancy Report	is a formal documentation submitted by the investigator to the sponsor (and potentially to regulatory authorities and ethics committees) when a clinical trial participant or a partner of a participant becomes pregnant during the course of a trial. The report includes relevant clinical details, expected date of delivery, follow-up plans, and the outcome of the pregnancy.
65. Single Joint Ethics Review Board	This Standard Operating Procedure (SOP) outlines the processes followed by the (SJREB) in reviewing and managing post-approval submissions from Coordinating Principal Investigators. These submissions may include notifications, amendments, progress reports, safety reports, or other post-approval documents related to ongoing research studies.
66. Meeting Agenda	is a structured list of topics, issues, or activities to be discussed or acted upon during a meeting.
67. Meeting Minutes	are the written record of what was discussed, decided, and assigned during a meeting. They typically include: ● Date and time of the meeting ● List of attendees ● Summary of discussions ● Decisions made ● Action items and who is responsible ● Next steps or upcoming meetings
68. Communication Records	refer to documented exchanges of information between parties, including emails, letters, memos, instant messages, and meeting summaries.
69. Management of Active Study Files, Documents and Records	This refers to the systematic organization, storage, and maintenance of all documents and records related to an ongoing study (e.g., clinical, academic, or scientific). It includes version control, access permissions, regular updates, and ensuring compliance with regulatory or institutional requirements.
70. A protocol database	is a centralized, structured repository that stores detailed information on protocols (formal plans or procedures for

research studies, experiments, clinical trials, etc.). It typically includes:

- Study title
- Objectives
- Investigators
- Methodologies
- Approval statuses
- Key dates

II. List of Annexes:

Chapter 1:	
Form Number	**Title of the Form**
None	Job Description of IRB Chair
None	Job Description of IRB Vice Chair
None	Job Description of IRB Member Secretary
None	Job Description of IRB Members
None	Job Description of IRB Secretariat (IRB Assistant and IRB Admin Staff)
Form 1.1A	Appointment of Independent Consultant
Form 1.1B	Appointment of Non-Affiliated Member
Form 1.1C	Appointment of Lay Member
Form 1.1D	Appointment of Lay & Non-Affiliated Member
Form 1.2	Curriculum Vitae and Training Record
Form 1.3A	Confidentiality & Conflict of Interest Agreement
Form 1.3B	Confidentiality & Conflict of Interest Agreement
Form 1.4	IRB Training Record
None	IRB Review Fee and Service Fees Table
Chapter 2:	
Form 2.1A	Application Form for Protocol Review - Initial Submission
Form 2.1B	Application Form for Protocol Review - Resubmission
Form 2.1C	Application Form for Protocol Review – Amendment
Form 2.4	Requirement Checklist Resubmission/ Amendment Protocol
Form 2.5	Protocol Summary
Form 2.6	Type of Review
Form 2.7A	Protocol Information

Form 2.7B	Protocol Evaluation Form for Initial
Form 2.7C	Protocol Evaluation Form for Resubmission
Form 2.7D	Protocol Evaluation Form for Community Research
Form 2.8	Informed Consent Evaluation Form
Form 2.9	Notification of IRB Decision
Form 2.10	Certificate of Approval
Form 2.11	Device Assessment Form (form 2.11) (Supplementary Forms 2.1A & 2.7B, 2.8)
None	MMC-Informed Consent Template-Guidelines
None	Confidentiality and NDA for Non-MMC Staffs and Members
Chapter 3:	
Form 2.9A	Notification Of IRB Decision - Protocol Deviation /Violation
Form 2.9B	Notification of IRB Decision - Final Report
Form 2.9C	Notification of IRB Decision - Progress Report
Form 2.9D	Notification of IRB Decision - Site Visit Report
Form 2.9E	Notification of IRB Decision - Serious Adverse Event Report (Form 2.9e
Form 2.9F	Notification of IRB Decision - Early Study Termination
Form 2.9G	Notification of IRB Decision - Participant's Request/ Query
Form 2.10A	Approval Letter (Amendments)
Form 3.1A	MMC-IRB Serious Adverse Event Report
Form 3.1B	Serious Adverse Event Report Reviewer's Recommendation Form (Form 3.1B) Onsite Report
Form 3.2	Protocol Amendment Review
Form 3.3A	Continuing Review Application
Form 3.3B	Progress Report Evaluation Form
Form 3.4	Final Report
Form 3.5	Deviation/ Non-Compliance/ Violation Report
Form 3.6	Request/ Query Record
Form 3.7	Site Visit Report
Form 3.8	Early Study Termination
Form 3.9	Expired Study Report
Form 3.10	Request For Closure of Expired Protocol
Form 4.6	Notification Evaluation Form

Form 4.7	Notification of IRB Decision – Notification
Form 4.8	Response to Post-Approval Modification
None	Post Approval Guidelines
None	Reminder Letter Form
None	SJREB SOP on Joint Review of Post-Approval Submission
Chapter 4:	
Form 4.1	Agenda of the Meeting
Form 4.2	Minutes of the Meeting
Form 4.3	Confidentiality Agreement Form For Non-Members Requesting To Access Makati Medical Center IRB Documents

III. References:

1. *World Health Organization. (2000). Operational guidelines for ethics committees that review biomedical research.* https://iris.who.int/handle/10665/66429
2. *World Medical Association. (2002). WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks [Original document].*
3. *World Medical Association. (n.d.). WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks [Annotated copy].*
4. *World Health Organization. (2011). Standards and operational guidance for ethics review of health-related research with human participants.* https://www.who.int/publications/i/item/9789241502948
5. *Food and Drug Administration. (2012). FDA Circular 2012-007: Recognition of ethical review board committee (ERB/ERC) for purposes of the conduct of clinical trials on investigational medicinal products in the Philippines and for other purposes.* https://www.fda.gov.ph/wp-content/uploads/2021/08/FDA-Circular-No.-2012-007.pdf
6. *Food and Drug Administration. (2013). FDA Circular 2013-018: Adoption of the International Conference on Harmonization (ICH) Safety and Efficacy Guidelines.* https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Circular-No.-2013-018.pdf
7. *Food and Drug Administration. (2013). FDA circular no. 2013-020: Reiteration of human cells, tissues, and cellular and tissue-based products.* https://www.fda.gov.ph/wp-content/uploads/2021/08/FDA-Circular-No.2013-020.pdf
8. *Food and Drug Administration. (2013). Registration of human cell-based products.*
9. *John Hopkin's Medicine Office of Human Subjects Research – Institutional Review Board. (2016). Reporting Protocol Deviations Retrieved From*

https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/protocol_deviations.html

10. *Council for International Organizations of Medical Sciences. (2016). International ethical guidelines for health-related research involving humans.* https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

11. *Philippine Health Research Ethics Board. (2017). PHREB resolution on the review of research proposals on COVID-19.* https://ethics.healthresearch.ph/index.php/registration-and-accreditation
12. *Philippine Health Research Ethics Board. (2020a). PHREB Resolution No. 20-002. Philippine Health Research Ethics Board.*
13. *Philippine Health Research Ethics Board. (2020b). PHREB Resolution No. 20-003. Philippine Health Research Ethics Board.*
14. *Philippine Health Research Ethics Board. (2020c). PHREB Resolution No. 20-004. Philippine Health Research Ethics Board.*
15. *Philippine Health Research Ethics Board. (2020d). PHREB Resolution No. 20-005. Philippine Health Research Ethics Board.*
16. *Philippine Health Research Ethics Board. (2020) PHREB resolution on COVID-19 research proposals.*
17. *PHREB STANDARD OPERATING PROCEDURES (2020) Retrieved From https://ethics.healthresearch.ph/index.php/phoca-downloads/category/19-2020-phreb-sop-workbook*
18. *Philippine Health Research Ethics Board. (2021). PHREB Resolution No. 21-001. Philippine Health Research Ethics Board.*
19. *Department of Science and Technology – Philippine Council for Health Research and Development. (2022). 2022 national ethical guidelines for health and health-related research.* https://www.pchrd.dost.gov.ph/publications/2022-national-ethical-guidelines/
20. *World Health Organization. (2023) WHO tool for benchmarking ethics oversight of health-related research involving human participants. https://www.who.int/publications/i/item/9789240076426*
21. *World Medical Association. (2024). WMA Declaration of Helsinki – Ethical principles for medical research involving human participants.* https://irb.makatimed.net.ph/wp-content/uploads/2025/04/2024-Declaration-of-Helsinki-4.pdf
22. *Declaration of Helsinki. (2024). World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/*

23. *Declaration of Helsinki. (2024). Key changes to the WMA Declaration of Helsinki 2024 [Summary document].*

24. *Republic of the Philippines Department of Health Single Joint Research Ethics Board. (2024) JOINT REVIEW OF INITIAL SUBMISSIONS, JOINT REVIEW OF POST-APPROVAL SUBMISSIONS retrieved from https://drive.google.com/drive/folders/1LatiEXRFrMjl5Y6GcUAAohb-mmYxiFgi*

25. *Republic of the Philippines Department of Health Single Joint Research Ethics Board Standard Operating Procedures effective date September 2024.*

26. *International Council for Harmonisation. (2025). ICH harmonised guideline: Guideline for good clinical practice E6(R3).* https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf

IV. History for Chapters 1 to 5:

Version Number	Date	Authors	Chapter	Change/s
9	TBD	Carolyn A. Butler, M.D., Mr. Joshua Jaime P. Nario, MA, RN, Rocelle F. Surat, CLSSYB	1	1. Broaden the Objectives and Responsibilities in Chapter 2: 2. Specify the IRB Admin Staff and IRB Secretariat Functions: - **IRB Admin Staff:** Responsible for administrative tasks like receiving and logging protocol submissions, scheduling meetings, distributing agendas, and maintaining records. - **IRB Secretariat:** Manages workflow, communication with stakeholders, training, and ensures compliance with policies and regulations, while also overseeing quality assurance and audit preparations. 3. The term "Honorarium" has been replaced with "Service Fees" to comply with the hospital's guidelines. 4. Revised the Form 1.2 Curriculum Vitae into Form 1.2 Curriculum

				Vitae and Training Form. The form now combines the original curriculum vitae with additional sections for documenting relevant ethics training, certifications, and professional development, ensuring IRB members qualifications are thoroughly recorded. 5. A new section listing all appendices and attachments for easy reference. 6. All citations and references have been revised to ensure accuracy and compliance with current guidelines.
9	TBD	Carolyn A. Butler, M.D., Mr. Joshua Jaime P. Nario, MA, RN, Rocelle F. Surat, CLSSYB	2	1. Broaden the Scopes, Objectives and Responsibilities in Chapter 2: 2. Establishment of a specified deadline for the submission of completed requirements pertaining to previously incomplete submissions. 3. Specify the IRB Admin Staff and IRB Secretariat Functions: - **IRB Admin Staff:** Responsible for administrative tasks like receiving and logging protocol submissions, scheduling meetings, distributing agendas, and maintaining records. - **IRB Secretariat:** Manages workflow, communication with stakeholders, training, and ensures compliance with policies and regulations, while also overseeing quality assurance and audit preparations.

				4. Revised the process to include only electronic submissions will be accepted and added timelines for all types of submissions. 5. Added a section that all IRB members may be given a copy of the protocol if they requested. 6. Revised statements that the PI may be invited during meeting discussions. 7. The SPARES and Expedited reviews are merged into one section. 8. Revised Review and assignment coordination to include that independent consultant may be invited to assist for review determined by the Chair. 9. Revised process of requirements for protocol review - (MMCIRB Reform was replaced by Letter of Endorsement signed by the Department Head of the Technical Review.) - Informed Consent Guidelines Template may be used for the investigator-initiated protocols. 10. Added process for requiring Memorandum of Agreement to Non-Makati Medical Center Institutions. 11. Revised the Meeting schedule for full board review starting at 9:00 am until 1:00/2:00 in the afternoon. 12. Revised the Protocol Review Fee amounting to 60,000 to 67,200.00 (net of withholding tax) for

				sponsor-initiated protocols and Php 33,600.00 (net of withholding tax) for investigator-initiated protocols. 13. Revised the Clinical Trial Agreement from 120,000.00 to 134,000.00 net of witholding tax. 14. Specify the process of Clinical Trial Agreements. 15. Review the Single Joint Research Ethics Board (SJREB) Review process. 16. Added the scope for that this SOP will be limited to review of protocols during a pandemic and align the criteria for cross referencing type of reviews for expedited and full board to all pandemic protocols. Added timelines for review for reviewing pandemic protocols. 17. A new section listing all appendices and attachments for easy reference. 18. All citations and references have been revised to ensure accuracy and compliance with current guidelines.
9	TBD	Carolyn A. Butler, Mr. Joshua Jaime P. Nario, Margaret Zoe J. Rañeses, RPm, CLSSYB, Ann Pauline R. Dela Cruz, CLSSYB, Rocelle F. Surat, CLSSYB	3	1. Expanded the Objectives to cover notification, amendment, continuing review, and post-approval monitoring processes. 2. Extended the Scope to include all submission types (notification, amendment, continuing review, post-approval).

				3. Clarified roles for Secretariat, Primary Reviewers, IRB Chair, and Administrative Staff. 4. Added and refined key terms (e.g., Notification Submission, Full Board Review, Business Arising, DSUR, Site Closure, End of Trial, Pregnancy Report). 5. The SOP now includes formalized procedures for assessing and collecting fees associated with amendment reviews and progress report reviews. 6. The SOP has been updated to incorporate the Business Arising process, detailing the identification, documentation, and review of unresolved submission items at subsequent Full Board Meetings. 7. The SOP has been revised to include the process for handling Notification Submissions, including procedures for submission, completeness screening by the Secretariat, and review by the Primary Reviewers and Full Board. 8. The SOP for the Single Joint Review of Post-Approval Submissions by the SJREB has been incorporated into and aligned with the SOP of the MMC-IRB. 9. All citations and references have been revised to ensure accuracy and compliance with current guidelines.
9	TBD	Carolyn A. Butler, Mr. Joshua Jaime P. Nario,	4	1. Revised the SOP to describe the measures to manage COI of members during the meeting

		Margaret Zoe J. Rañeses, RPm, CLSSYB, Ann Pauline R. Dela Cruz, CLSSYB, Rocelle F. Surat, CLSSYB		(i.e., declaration, recusal, documentation in minutes of the meeting) 2. Revise the SOP to include the preparation of the communication records. 3. Stated the required contents of electronic folders of IRB. 4. Added sections regarding management of confidential files and included statements that this will be accessed with a password protection measures. 5. Modify the protocol labeling format. 6. Revised the Inactive Protocol File management to include how the inactive protocols and active protocols will be managed. 7. Included content from submission trackers.
9	TBD	Carolyn A. Butler, Mr. Joshua Jaime P. Nario, CLSSYB, Rocelle F. Surat, CLSSYB	5	1. Clarified the objectives, scope, and responsibilities outlined in the Standard Operating Procedure (SOP). 2. Added definitions for key terms. 3. Specified the procedures for voting and decision-making regarding the review of the SOP. 4. Detailed the process for distributing the revised SOP. 5. Included a timeline for the dissemination of the approved SOP.