APPENDICES:

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

<table>
<tr><th>Term</th><th>Definition</th></tr>
<tr><td>1. Institutional Review Board (IRB)</td><td>An independent committee established by Makati Medical Center under the Medical Director to review and oversee research involving human participants.</td></tr>
<tr><td>2. Research Protocol</td><td>The protocol is the definitive document of the research or study. It guides those who will conduct the research, reference for evaluators and reviewers, template for validation, substantiation for intellectual property claims, and the legacy of the proponent. Therefore, it should be rigorously conceptualized, carefully crafted, and elegantly formulated</td></tr>
<tr><td>3. Memorandum of Agreement (MOA)</td><td>A formal document detailing cooperative responsibilities between MMC IRB and external entities.</td></tr>
<tr><td>4. Ethical Review</td><td>The process of evaluating research protocols to ensure adherence to ethical standards and protection of participant rights.</td></tr>
<tr><td>5. Full Board Review</td><td>Is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.
A comprehensive review of research posing more than minimal risk, conducted by the convened IRB.
<table>
<tr><th>ISFB</th><th>FULL BOARD REVIEW</th></tr>
<tr><td>1</td><td>Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3)</td></tr>
<tr><td>2</td><td>Phase 4 intervention research involving drugs, biologics or device</td></tr>
<tr><td>3</td><td>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</td></tr>
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	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

6. Expedited Review

Is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

A faster review process for minimal-risk studies conducted by designated IRB members.

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 <u>not</u> 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

7. Medical / Scientific Members

These are individuals with academic degrees in the medical profession and a master's in the nursing profession.

8. Non-Medical / Scientific Members	These are individuals without academic degrees in the medical profession nor a master's degree in the nursing profession.
9. Non-Medical / Non-Scientific Members	These are individuals whose primary interest is not in any of the natural, physical and Social sciences and whose highest formal education is a bachelor's degree.
10. Alternate Members	Individuals who possess the qualifications of specified regular members. They are called to attend a meeting and substitute for regular members to comply with the quorum requirement when the latter cannot attend the meeting.
11. SPARES	Subcommittee Panels for Minimal Risk Research Protocols, composed of regular MMC IRB members. SPARES are designated subcommittees assigned to review minimal-risk research.
12. Serious Adverse Event (SAE)	Any untoward or undesirable medical occurrence in a research participant or patient in a clinical investigation after use or administration of an investigational product (ICH-GCP). See also Adverse Drug Reaction, Serious Adverse Event, and Suspected Unexpected Serious Adverse Reaction
13. Good Clinical Practice (GCP)	Good Clinical Practice (GCP) Guidelines an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects; compliance with these standards provide public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the International Declaration of Helsinki, and that the clinical trial data are credible (ICH-GCP).
14. Compassionate Use	Permission given by the national regulatory authority in particular the FDA, to make investigational new drugs and devices that are not yet approved for marketing, for use of very or terminally ill research participants having no other treatment alternatives.
15. Stem Cell Therapy	A procedure that uses stem cells to treat or prevent diseases or conditions.
16. Standard of Care	Healthcare intervention or regimen that is generally accepted by health practitioners and experts as beneficial to an individual needing such care.

17. PHREB	Philippine Health Research Ethics Board – the national policymaking body on health research ethics in the Philippines.
18. PHREB Resolution No. 20-001	A 2020 resolution allowing RECs to modify SOPs and conduct online reviews during the COVID-19 pandemic.
19. COVID-19	A viral respiratory disease caused by SARS-CoV-2, with public health implications affecting research and IRB procedures.
20. Exempt from Review	Protocols meeting criteria that exclude them from IRB review (e.g., case reports, QA/QI studies, meta-analyses without identifiers).

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

21. Principal Investigator	Is the lead implementer of the clinical trial protocol. "Co-Investigators" (Co-Is) are a subset of key personnel with special clinical trial responsibilities.
22. Protocol Screening	The process of determining the appropriate type of review and assigning protocol reviewers.
23. Designated Staff of Research Team	A delegated administrative staff member allowed to submit or inquire about IRB matters on behalf of the PI. Providing members of the research team with sufficient oversight, training, and information to facilitate appropriate safety procedures and protocol adherence;
24. Clinical Research Officer/Assistant	Staff from a Clinical Research Organization tasked with submitting documents and coordinating IRB-related activities.
25. Coding	The assignment of an official MMC IRB code to a new protocol submission.
26. Electronic Log Book	A digital record of all submissions received, including dates, sender names, and receiving staff.
27. Electronic Master List Database	A restricted-access database within MMC's intranet for tracking all approved protocols.

	A collection of information (e.g. regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.
28. Memorandum of Agreement (MOA)	A formal document detailing the cooperative arrangement between the institution and external parties.
29. Electronic Protocol Folder	A secure cloud-based folder containing all protocol submission files.
30. Official Email	The IRB-dedicated MMC email used for confidential communication and document handling.
31. Type of Review	Classification of review as Full Board, Expedited, or Exempt based on protocol content and risk level.
32. Primary Reviewers	A member of the Research Ethics Committee (usually a scientist and a non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee.
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	The MMC IRB strictly adheres to quorum requirements prescribed by national and international ethics guidelines (e.g., NEGHHR 2022, CIOMS, ICH-GCP). A quorum must be established to conduct a review and make decisions validly during convened meetings. A quorum is considered present when the following conditions are met: • At least 50% plus one of the total IRB memberships is in attendance.

	• At least one lay member and one non-affiliated member are present. • For protocols involving pediatric populations, a pediatrician or child development expert must be in attendance
40. Conflict of Interest	a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.
41. Agenda of the Meeting	is the order of business that includes the list of topics or items approved for discussion in a meeting by the REC Members in a regular or special meeting.
42. Minutes of the Meeting	The official narration and record of the proceedings of the assembly of REC Members, based on the agenda.
43. Approved Protocols	Protocols that have passed IRB evaluation and are cleared for implementation.

44. Full Board Review

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

45. Expedited Review

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

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. Monthly Safety Subcommittee Meeting (MSS)	The Therapeutics and Medication Safety Committee serves as the institution's policy-recommending body, tasked with monitoring and evaluating adverse drug reactions, including those associated with biologics and vaccines, within the healthcare setting. The committee develops recommendations aimed at preventing these occurrences. Furthermore, the Institutional Review Board is responsible for reporting all Safety Adverse Events to this committee.
49. 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.
50. Suspected unexpected serious	serious adverse reaction in research participants who were given a drug, which may or may not be dose related, but are not

<table>
<tr><td>adverse reactions (SUSARs)</td><td>expected or anticipated since these reactions are not consistent with current information about the medicinal product in question.
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.</td></tr>
<tr><td>51. Protocol Deviation</td><td>Non-compliance with the approved protocol that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.</td></tr>
<tr><td>52. Protocol Violation</td><td>Non-compliance with the approved protocol that increases risk or decreases benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.</td></tr>
<tr><td>53. FOR EXPEDITED REVIEW (WITH MINOR AMENDMENT)</td><td>
<table>
<tr><th>RSER</th><th>EXPEDITED REVIEW (SPARES)</th></tr>
<tr><td>Q</td><td>● Protocol amendments that have minor modifications and no significant risk to study participants, such as:</td></tr>
<tr><td>1</td><td>● Administrative revisions, such as correction of typing errors</td></tr>
<tr><td>2</td><td>● Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.</td></tr>
<tr><td>3</td><td>● The research activity includes only minor changes from previously approved protocol.</td></tr>
<tr><td>4</td><td>● Minor protocol amendments that do not change the risk/ benefit assessment</td></tr>
</table>
</td></tr>
<tr><td>54. FOR FULL BOARD REVIEW (WITH MAJOR AMENDMENT):</td><td>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</td></tr>
</table>

- 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

55. A site visit	is an activity of the REC where an assigned team goes to the research site or office for specific monitoring purposes. Site visits form is part of the MMC IRB's post approval monitoring program to ensure that research is conducted ethically, in compliance with approved protocols, and with full protection of participant rights and welfare. Visits may be routine or for cause and are performed by designated members of the IRB.
56. A final report	The Final Report is a summary of the outputs and outcomes of the study upon its completion. The REC requires the accomplishment of the Final Report form within a reasonable period after the end of the study. It also signifies the formal conclusion of a research study approved by the Makati Medical Center Institutional Review Board (MMC IRB). Submission and evaluation of the Final Report ensure that all protocol activities have been completed, study-related obligations have been fulfilled, and any final outcomes, ethical considerations, or data responsibilities have been addressed.
57. Early study termination or withdrawal	If a study is prematurely ended, the research must arrange for the appropriate management of participants who have already been recruited, including notifications. In the case of a clinical trial that is prematurely terminated or suspended for any reason, the principal investigator shall promptly inform the REC

	how this shall be managed and ensure appropriate therapy and follow-up of participants. The researcher shall submit a written, detailed explanation of the termination or suspension in all cases.
58. Annual Report or Continuing Review	The Annual/Progress Report description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Forms. The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the REC based on the level of risk.
59. Notification	Submissions refer to post approval updates that must be reported to the IRB even if they do not require prior IRB approval. These submissions ensure continuous oversight of study safety, compliance with regulatory requirements, and alignment with institutional policies. Notifications must be submitted within the prescribed timelines set by the IRB, regulatory agencies, and applicable international guidelines.
60. 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.
61. Investigator's Brochure	The Investigator's Brochure (IB) is a compilation of the clinical and nonclinical data on the investigational product(s)1 that are relevant to the study of the product(s) in human participants. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for and their compliance with many key features of the protocol, such as the dose, dose frequency/interval, methods of administration and safety monitoring procedures.
62. 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.
63. 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.
64. 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.
65. 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.
66. 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.
67. Meeting Agenda	is a structured list of topics, issues, or activities to be discussed or acted upon during a meeting.
68. 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
69. Communication Records	refer to documented exchanges of information between parties, including emails, letters, memos, instant messages, and meeting summaries.
70. 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.

71. 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 Alternate Member
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
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:

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IV. History for Chapters 1 to 5:

Version Number	Date	Authors	Chapter	Change/s
10	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. 7. Changed the Independent Consultant to Alternate Members. 8. Revise the Chapter 1 Section IV to add the Data Privacy Act -PHREB Accreditation Policies
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 maybe 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 Alternate member 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 withholding 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 protcols. 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.
10	TBD	Carolyn A. Butler, Mr. Joshua Jaime P. Nario, Ann Pauline R. Dela Cruz, CLSSYB,	3	1. Expanded the Objectives to cover notification, amendment, continuing review, and post-approval monitoring processes.

		Rocelle F. Surat, CLSSYB		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.
10	TBD	Carolyn A. Butler, Mr. Joshua Jaime P. Nario, Ann Pauline R. Dela Cruz, CLSSYB, Rocelle F. Surat, CLSSYB	4	1. Revised the SOP to describe the measures to manage COI of members during the meeting (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 measure. 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. 8. The SOP has been revised to state that the business arising from the previous meeting will be summarized in table form and discussed in the agenda and minutes of the meeting template.
10	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.