Chapter III : Post Approval Monitoring	Document Code: **IRB-SOP-1120-PAM-003-08**	
	Effective Date: June 28, 2021	Page: Page 1 of 38
Issued by: **Institutional Review Board**	Approved by: *(original document signed)* **SATURNINO P. JAVIER, M.D.** **(Medical Director)**	
☐ New	Supersedes: IRB-SOP-0916-PAM-003-07	Dated: June 09, 2021

Supersedes:	IRB-SOP-0916-PAM-003-07
Authored by:	MMC SOP Team (adapted from the DOH SOP)
Effective Date:	June 28, 2021
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Approval Date:	June 15, 2021

***REVIEW: This Standard Operating Procedure is reviewed every 3 years or earlier as indicated.**

Purpose

To describe the post approval activities of the Makati Medical Center Institutional Review Board (MMC IRB) to the events reported by the principal investigator to MMC IRB. Submissions are required by IRB during the conduct of the study. The period covered begins after approval has been granted by the MMC IRB until the completion of the study at the IRB approved site.

3.1 Serious Adverse Events

3.1.1 Purpose

To describe the IRB review procedures for serious adverse events

3.1.2 Scope

This SOP applies to the review of all adverse event reports (including Serious Adverse Event and Suspected Unexpected Serious Adverse Reaction reports) submitted by investigators and sponsors to the Makati Medical Center IRB to comply with ICH GCP. The IRB reviews such reports to determine appropriate action to protect the safety of participants in an approved study. The terminology used for the reporting of adverse drug events is based on the Suspect Adverse Reaction Report Form (CIOMS Form I), FDA Philippines.

ICH-GCP E6 defines a serious adverse event (SAE) or a serious adverse drug reaction (ADR) as any untoward medical occurrence that at any dose

A. results in death,
B. is life threatening,
C. requires hospitalization or prolongation of existing hospitalization,
D. results in persistent or significant disability or incapacity, or
E. results in a congenital anomaly or birth defect.

A suspected unexpected serious adverse reaction (SUSAR) is a serious event wherein the nature and severity of which is not consistent with the applicable product information. In the case of an unapproved investigational product, the event is not consistent with the Investigator's Brochure (IB). In the case of a licensed product, the event is not consistent with the approved package insert or summary of product characteristics.

This SOP also discusses the role of Adverse Events subcommittee in reviewing the serious adverse events reported to MMC IRB.

3.1.3 Responsibilities

A. The primary responsibility of the Makati Medical Center Institutional Review Board is to conduct an appropriate review of adverse event reports to ensure oversight over the safety of participants enrolled in the study.
   1) Ensures that investigators are made aware of its policies and procedures concerning SAE reporting.
   2) Sets up the necessary mechanisms to receive adverse event reports from investigators of researches that it has approved. A link is provided per protocol to enable investigators to submit the SAE and SUSAR reports online.
   3) Receives and reviews adverse event reports from its own site and takes the necessary action to ensure the safety of participants in the study.
   4) Receives SAE and SUSAR reports from other sites within and outside the country. It is the responsibility of the Makati Medical Center IRB to be updated about safety issues related to studies that it has approved which are also being conducted in other centers/sites.

B. The Makati Medical Center IRB has the authority to suspend or terminate approval of research at its site when the safety of participants is no longer assured. When Makati Medical Center IRB takes such action, it is required to provide the reasons for its action and to promptly report such decision to the investigator.

C. The functions of the SAE subcommittee are as follows:
   1) Ensures completeness of the SAE review forms.
   2) Monthly reporting of onsite SAEs to the IRB Full Bord meeting and Medication Safety Subcommittee meeting (MSS).
   3) Analyzes the history of the SAEs from previous SAE reports for each protocol to recommends appropriate actions to the Board (Eg. Amendment, Site visit).
   4) Provides substantial comments by referencing to the Investigator's Brochure, DSMB reports, checking onsite SAE history and trending offsite SAEs
   5) Summarizes onsite SAEs of each protocol every 6 months.
   6) Conducts at least once a year SAE subcommittee meeting to deliberate on the trending of onsite and off-site reports at least once a year and makes necessary recommendation to the Board for appropriate decision

3.1.4 Process Flow/Step

NO	ACTION	RESPONSIBILITY	TIMELINE
1	Acknowledge receipt of onsite Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs). ↓	Secretariat	1 working day
2	Summarize and distribute SAE/ SUSAR to Primary reviewers and AE Subcommittee ↓	Secretariat	1 working day
3	Review SAE and SUSAR and make necessary recommendations. ↓	Primary Reviewers and AE Subcommittee	1 working day
	Offsite | Onsite ↓		
	↓ | Immediate action if needed and report in Full Board ↓	Primary Reviewers AE Subcommittee Chair	1 working day
	Conduct AE Subcommittee meeting ↓	AE Subcommittee	1 working day
	Discussion and deliberation during Full Board Review. ↓	IRB Members	1 working day
4	Notify the principal investigator of the IRB decision. ↓	Secretariat	1 working day
5	File the SAE documents in protocol folder and electronic protocol folder, update the database, index and tracker.	Secretariat	1 working day

Detailed Instructions

3.1.4.1 Upon release of the approval letter, MMC IRB informs the investigators of the requirement to report SAEs and SUSARs using Form 3.1A or online submission within a specific time.
For ONSITE SAEs, online submission is within seven (7) days after recognition of the event. Printed copies of the online submission must be provided within seven (7) days after recognition of the event.
For OFFSITE SAEs, reports are submitted along with the progress report.

Reporting Time Frame:

a. Fatal or life threatening unexpected ADRs occurring in clinical investigation qualify for very rapid reporting. Regulatory agencies should be notified reporting (e.g., by telephone, facsimile, e-mail) not later than seven (7) calendar days after the first knowledge by the sponsor of that case followed by complete written report within eight (8) calendar days.
b. All other SAEs, SUSARs that are not fatal or life threatening must be filed by the IRB Secretariat as soon as possible but not later that fifteen (15) calendar days after the first knowledge by the sponsor that the case meets the minimum criteria for expedited reporting.
c. All the other adverse events, SUSARs, and DSURs will be reported as part of the annual progress report.
d. All Adverse Events reports to the IRB should be reported to the appropriate entities of the hospital if applicable or necessary (e.g., Therapeutics Committee, Quality Management Division, Medication Safety Subcommittee, etc.).

Upon receipt of submission, Secretariat checks the completeness and takes note of the timeliness of the report in the database. Late report will be notified and be given a reminder warning on the required timelines for reporting.

If everything is in order, Secretariat sends an acknowledgement receipt for the documents submitted.

Secretariat files the SAEs and SUSARs, logs the date of submission and updates the Database, index and tracker

3.1.4.2 Secretariat segregates and classifies the SAE/ SUSAR reports according to their origin or sites where they happened: Off-site and on-site. An “ONSITE STAMP” will be used for Onsite SAE reports.

Secretariat prepares a summary report per SAE/SUSAR per protocol and distributes (via email or printed copy) a copy of the onsite SAE report to the primary reviewers and AE Subcommittee members within 24 hours upon receipt of the report.

Offsite SAE / SUSARS are kept for the trending and analysis report by AE Subcommittee

IRB adopts appropriate response depending on the site where the SAE/ SUSAR happened. SAE Subcommittee members are provided with copies of SAE within 24 hours upon receipt.

3.1.4.3 AE Subcommittee is given 1 working day to review and provide recommendation using Form 3.1A or online submission and Serious Adverse Event Report Reviewer's Recommendation Form **(Form 3.1B)**.

For SAEs that occurred onsite, the Adverse Event Subcommittee Chair analyzes the investigator/ sponsor assessment (serious, related, and unexpected) and informs the Chair of the recommended action to ensure safety of participants.

All onsite SAEs are reported in the full board meeting for discussion.

Adverse event assessment is guided by the following:

- SAE is UNLIKELY or UNRELATED to the study drug or device – the report is forwarded to the AE subcommittee for analysis of trend and causality
- SAE/ SUSAR is DEFINITELY, POSSIBLY or PROBABLY related to the study drug or device – the report is forwarded to the AE subcommittee for analysis and determination if immediate action is necessary. If immediate action is warranted, the report with recommendations is forwarded to the chair.
- For multicenter, national studies, note the nature (related or expected) of the SAE/ SUSAR and discuss among AE subcommittee for recommendation and reports to IRB full board for the final decision.
- For multicenter, international studies, note the trend of occurrence of SAE/ SUSAR in study sites in foreign countries and other local site.

SAE and SUSAR are discussed and reviewed during Makati Medical Center IRB full board meeting for appropriate action as follows:

1) Request an amendment to the protocol or consent form
2) Request further information
3) Suspension of:
   a. Enrollment of new research participants until further review of the IRB.
   b. All trial-related procedures (except those intended for safety and well-being of the participant) until further review by the IRB.
4) Termination of the study
5) Take note and continue monitoring
6) Site Visit

All comments related to SAE are documented and kept on file and assigned Primary reviewers are updated.

3.1.4.4 Investigator is informed by Secretariat about the IRB decision and recommendation through notification of IRB decision **(Form 2.9E)**.

3.1.4.5 Secretariat updates the database, index and tracker accordingly.

3.2 Protocol Violation/ Protocol Deviation

3.2.1 Purpose

To describe the IRB review procedures for protocol violation/ deviation

3.2.2 Scope

A 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:

A. 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
B. 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.

This SOP applies to all MMC-affiliated investigators with protocols conducted in and outside Makati Medical Center (MMC). This specifies appropriate actions to ensure compliance.

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.

3.2.3 Responsibility

It is the responsibility of the IRB Secretariat to receive protocol violation/ deviation reports submitted to the IRB.

It is the responsibility of the board members or designated reviewers to assess and recommend necessary actions related to protocol violation/ deviation.

The primary responsibility of the MMC IRB is to ensure all investigators comply with International Conference on Harmonization Good Clinical Practice (ICH GCP) and other standard guidelines in research.

3.2.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive and distribute the protocol violation/deviation reports **(Form 3.5)**	Secretariat	1 working day
2	Assessment of report and determination if it is a protocol deviation or protocol violation and its timely appropriate action needed.	Member-Secretary Chair	1 working day 1 working day
3	Review protocol deviation or violation report and recommend action	Primary reviewers	1 working day
4	Discuss at full board, make a decision and recommend appropriate action	Members/ Chair	1 working day
5	Notify the investigator of the decision	Secretariat/ Chair	1 working day
6	Keep records in protocol folder and update the database	Secretariat	1 working day
7	For protocol violations: Follow up the status of recommended action for reporting as business arising in the next full board meeting	Secretariat	1 working day (After 7 working days from the notice of decision)

Detailed instructions

3.2.4.1 Secretariat receives protocol violation or deviation reports **(Form 3.5)** for any event in the site that is not in compliance with the previously IRB approved protocol and related documents from investigators and other parties related.

Secretariat ensures the completeness of the information.

The protocol deviation or violation report is submitted within 2 months upon recognition by the principal investigator.

3.2.4.2 Protocol deviation or violation reports are forwarded to the Member Secretary and Chair for assessment and determination of type of review and action. All protocol deviation and violations are reported to full board for deliberation and decision.

Assessment is based on the classification of protocol deviation and protocol violation.

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
- Improper 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

Protocol deviation a less serious noncompliance which may not render the patient ineligible. It has no significant consequences. Deviation occurs when the activities on the study diverge from the IRB approved protocol, e.g. missing a visit window because the subject is travelling. It is not as serious as protocol violation. Protocol Deviations are classified accordingly:

PDFB	All protocol deviations are reviewed under Full Board. Classified accordingly:
1	Major protocol deviation (non-emergent/planned deviations that represent a major change in the approved protocol)
1.1	Exceptions to eligibility criteria
1.2	Exceptions to the form and manner of obtaining informed consent
1.3	Exceptions to schedule of administration of an investigational product
1.4	Planned, non-emergent deviations
2	Minor protocol deviation (does not affect the scientific soundness of the research plan or the rights, safety, or welfare of human subjects)
2.1	Administrative deviations
2.2	Logistical and schedule changes (reschedules or out of window visits, rescreening of participants, or re-administration of treatment or diagnostic procedures) in site visits

Reference: John Hopkin's Medicine Office of Human Subjects Research – Institutional Review Board. (2018). Reporting Protocol Deviations. Retrieved from: https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/protocol_deviations.html

3.2.4.3 Protocol deviation or violation reports are forwarded to the initial primary reviewers for assessment and recommendation. Assessment forms are returned to Secretariat.

Monitoring of protocol deviations and violations are part of the post approval continuing oversight function of the IRB through the assigned reviewers. In cases that the original primary reviewers are no longer a member of the IRB, the Chair will be asked to do the review of the deviations/violations.

3.2.4.4 All reports of protocol deviations and violations for the month are reported to the full board meeting for proper assessment and decision as to the recommended corrective preventive measures.

Issues as well as the details of non-compliance involving research investigators are included in the agenda of the IRB meeting for Board recommendation and decision.

Frequent deviations especially research team-related are assessed. Corrective actions and further monitoring are required.

Board Decision

A. Continue study and monitor compliance

B. Request for further information
C. For site visit
D. Amend protocol
E. Amend Informed Consent Form
F. Suspend the study* *(NB.* until the following are met:*
   1) Additional information is made available.
   2) *MMC IRB recommendations are implemented by the Principal Investigator and considered satisfactory by the MMC IRB.)*
G. Terminate approval of current study**
   *(NB** Termination is based on one or more of the following:*
   1) SAE reports that indicate significant and study related harm to participants
   2) Fraudulent violations and major breach of previously approved protocols that affects scientific integrity and safety of participants
   3) Implementation of major amendments with implications to participant safety and scientific integrity without approval by the MMC IRB
   4) Failure to respond to MMC IRB's request for information/action

Research proposal of an involved Principal Investigator or co-investigator are held in abeyance as determined by the Chair.

Criteria for Withdrawal of Approval

Approval may be withdrawn by the MMC IRB for the following reasons:

A. SAE directly or indirectly attributed to the research.
B. Breach of previously approved conduct of the research.
C. Major changes, deviation and amendments to the approved protocol without another approval by the MMC IRB
D. Failure to respond to MMC IRB's request for information/ action.

3.2.4.4 Notification of the Makati Medical Center IRB's decision

For the protocol deviation/ violation, the IRB Secretariat records the decision and prepare four (4) copies of the notification letter (cc investigator, the sponsor, relevant national authorities and institutions, and the IRB). The chair signs the notification.

3.2.4.5 All protocol deviation/violation records are filed in the protocol folder and the IRB database, index and tracker are updated accordingly.

3.2.4.6 Secretariat follows up the action implemented after 7 days from the Notice of Decision as stipulated in the letter to the principal investigator. This is part of the business arising on the next full board meeting

3.3 Site Visits

3.3.1 Purpose

To describe the Makati Medical Center Institutional Review Board (MMC IRB) procedures related to the conduct of site visits.

3.3.2 Scope

This SOP applies to any visit made in any study site, on behalf of the MMC IRB, to check compliance with Good Clinical Practice and MMC IRB approved protocol and related documents.

3.3.3 Responsibility

It is the responsibility of the MMC IRB to perform or designate some members or qualified representatives to perform on its behalf on-site visit of the research projects it has approved.

3.3.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Select the study sites and the site visit team.	IRB Members/ Chair	1 working day
2	Inform the principal investigator. Prepare the documents and other relevant information prior to site visit. Distribute to site visit team	Secretariat	1 working day
3	Site visit proper: check the onsite documents and compare with the current documents in the protocol file; interview the principal investigator and/or research staff	Site Visit Team	1 working day
4	Write a report and make a recommendation utilizing the Site Visit Report **(Form 3.7);** Present the findings and recommend appropriate action for the Full Board to decide	Site Visit Team	1 working day
5	Communicate the decision to the Principal Investigator and give Notice of Decision	Secretariat	1 working day

6	File the documents and update the database	Secretariat	1 working day

Detailed Instructions:

3.3.4.1 Selection of study sites

MMC IRB selects the study site according to the following criteria for site visit:

A. New study sites or new principal investigators
B. Reports of remarkable serious adverse events
C. High volume of studies carried out at the study site (frequent PI violation reports, number of participants, etc.)
D. Non-compliance or suspicious conduct (fraud, violation of rights of participants)
E. Frequent failure to submit progress and other required reports
F. Frequent protocol violations that affect participant safety and scientific integrity

MMC IRB members or Secretariat in consultation with the Chair may initiate an on-site evaluation of a study site for cause or for a routine audit. The Site Visit team consists of the following and are assigned by the IRB during the full board meeting:

A. A reviewer of the study
B. A member of the Adverse Event Subcommittee
C. An MMC IRB member assigned by the MMC IRB Chair

3.3.4.2 Before the visit

- Secretariat prepares the documents needed for the site visit and distributes to the Site Visit Team
- Secretariat formally communicates the schedule and the purpose of the site visit to the Principal Investigator
- MMC IRB Site Visit Team has the following responsibilities:

A. Review the MMC IRB files for the study and site
   1) Contact the site to notify them about the site visit.
   2) Coordinate the date and time for the site evaluation visit.
   3) Make the appropriate travel arrangements.
B. Make appropriate notes, or
C. Copy some parts of the files for comparison with the site files.

3.3.4.3 During the visit

A. Use the Site visit checklist **(Form 3.7)**
B. The MMC IRB Site Visit Team may conduct one or all of the following:
   1) Review the informed consent document to make sure that the site is using the most recent version,

2) Review randomly the subject files to ensure that subjects are signing the correct informed consent,
3) Observe consent process, if possible.
4) Check if the files are orderly and confidentiality is maintained
5) Interview the members of the research team/ investigator.
6) Debrief the principal investigator about site visit findings and comments.

3.3.4.4 After the visit

MMC IRB Site Visit Team

A. Writes a report/comment (**use Form 3.7**) within 1 week describing the findings during the audit.
B. Forwards a copy of the site visit to the Secretariat for inclusion in the next board meeting.
C. Sends a copy of the report to the site for their files, and
D. Places the report in the correct files.

Presentation of the site visit report

A. Present the site visit report to Full Board.
B. Board makes a decision about appropriate action.

Board Decision:

A. Continue study and post approval monitoring
B. Amend protocol
C. Amend Informed Consent
D. Stop recruitment
E. Terminate study
F. Blacklist Principal Investigator/ Sponsor
G. Recommend other corrective measures (specify)
H. Others (specify)

3.3.4.5 Secretariat communicates the board decision to the principal investigator for appropriate action utilizing Notification of IRB Decision **(Form 2.9D)**.

Secretariat reports the investigator's action and response to the Notice of Decision and recommendation. This is part of the business arising during the next Full Board meeting.

3.3.4.6 Secretariat keeps a copy of the files and updates IRB database accordingly.

3.4 Amendments

3.4.1 Purpose

To describe the IRB review procedures for amendments of the protocol and related documents

3.4.2 Scope

This SOP applies to previously approved study protocols and related documents that are being amended later and submitted for approval by the Makati Medical Center IRB. Any amendment of the study related documents may not be implemented until reviewed and approved by the IRB.

3.5.3 Responsibilities

It is the responsibility of the IRB Secretariat to manage protocol amendment package submitted by the principal investigator.

It is the responsibility of the original primary reviewers to review the amendments and recommend appropriate action. In cases that the original primary reviewers are no longer a member of the IRB, the Chair will be asked to do the review of the amendment.

It is the responsibility of the IRB Chair to determine whether the amendment goes to expedited or full board review. The IRB approves the final decision for amendments submitted by the principal investigator to the IRB.

3.5.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive amendment package including application **(Form 2.1C)** and documents for amendment **(refer to Form 2.4);** Acknowledgement Receipt is provided; Document tracker is updated ⬇	Secretariat	1 working day
2	Determine type of review for the amendment **(Form 2.6)** ⬇	Member-Secretary Chair	1 working day 1 working day

3	Distribute amendment to the original primary reviewers/ IRB members	Secretariat	1 working day
4	Review amendment and make a recommendation **(Form 2.9)**	Primary reviewers/ IRB Members	1 working day
5	Discuss at Full Board/SPARES for decision if necessary	Members	1 working day
6	Inform investigator about IRB decision **(Form 2.9)**	Chair/ Secretariat	1 working day
7	Keep a copy of all amendment related in the protocol file	Secretariat	1 working day
8	Update index **(Form 4.5)** and tracker **(Form 4.4A and 4.4B)** and database	Secretariat	1 working day

Detailed Instructions

3.4.4.1 Secretariat properly informs investigators on the procedure for amendment which includes the submission of an amendment application (**Form 2.1C and Form 3.2)** whenever there is any change regarding the composition of the study team, the study site and the protocol related documents for approvals previously granted by the IRB.

Secretariat checks the completeness of the amendment package submitted by the Investigator using Requirement Checklist - Amendment **(Form 2.4)**.

Section 3.4 Amendments ed and this starts the turn around time for approval of amendments from the submission of amendment to the release of Notice of Decision

3.4.4.2 Member-secretary recommends the type of review utilizing **Form 2.6**,

Chair approves type of review (e.g. full board or expedited) based on the following criteria and guideline

FOR EXPEDITED REVIEW (WITH MINOR AMENDMENT):
Amendments on the protocol which have been initially approved under expedited review with minor changes will undergo expedited review by the original primary reviewers.

RSER	EXPEDITED REVIEW (SPARES)
	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

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:

1) a change in study design
2) additional treatments or the deletion of treatments
3) any change in the inclusion/exclusion criteria
4) change in method of drug intake or route of drug intake (e.g. oral changed to intravenous)
5) significant change in the number of subjects (increase or decrease in sample size that alters the fundamental characteristics of the study)
6) 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

3.4.4.3 Secretariat distributes the amendment package to the original primary reviewers

3.4.4.4 Original primary reviewers check the amended documents and compare them with the previously IRB approved documents in the protocol files.

Amendments are checked if it would alter the risk/ benefit ratio of the study to make appropriate recommendations using **Form 3.2.**

EXPEDITED REVIEW: If only minor changes are involved in the amendment and has been determined for expedited review, the reviewer's recommendation becomes the basis for the final decision of the IRB and a letter granting approval is prepared by the IRB Secretariat.

FULL BOARD REVIEW: If major changes are involved in the amendment (alters the risk/ benefit ratio of the study), the amendment is referred to full board after review by the primary reviewers.

3.4.4.5 Amendments for expedited or full board review are both reported during the full board meeting. Expedited review decision is reported in full board meeting while amendments for full board decision are discussed during the full board meeting.

Decision points both for expedited and full board review are as follows:

A. Request for clarification/ more information, to elaborate or explain further the amendments.
B. Approval
C. Recommend major changes to the protocol/ Informed Consent Form
D. Recommend minor changes to the protocol/ Informed Consent Form
E. Disapproval
F. Pending Decision

*The board may decide to re-consent the participants currently enrolled in the study when needed.

3.4.4.6 Secretariat prepares the Notification of IRB Decision **(Form 2.9)** to inform the investigators about the board decision. The Secretariat forwards the Notification of IRB Decision **(Form 2.9)** to the investigators for proper action.

3.4.4.7 Secretariat keeps a copy of all amendment related documents in the protocol files and updates IRB database, index **(Form 4.5)**, and document tracker **(Form 4.4A and 4.4B)** accordingly.

3.5 Progress Report

3.5.1 Purpose

To describe the IRB review procedures for progress and annual report. This includes the periodic review of the protocols previously approved by the IRB and the post approval monitoring parameters to assess renewal of approval by providing recommendations regarding the criteria, process, and frequency (not less than annually) of continuing review to assure the protection of the rights and welfare of human subjects enrolled in clinical investigations.

3.5.2 Scope

This SOP provides instructions for the review of progress reports that are required by the Makati Medical Center IRB to be submitted by the principal investigator to monitor the safety of participants enrolled in a study.

1) The annual report becomes the basis for continuing review of protocols whose approval needs to be renewed every year.
2) This SOP applies to the conduct of any continuing review of study protocols involving human subjects at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the IRB may choose to review or monitor the protocols more frequently.

3.5.3 Responsibility

It is the responsibility of the investigator to maintain the approval of the study protocol by submitting a continuing report or amendment prior to the expiration of IRB approval. The Principal Investigator is given a grace period until 12 working days post expiration date of approval to submit a progress report for the renewal of IRB approval. Failure to submit a progress report will automatically INACTIVATE the status of the study.

It is the responsibility of the Makati Medical Center IRB Secretariat to remind investigators to submit the progress and final reports **(Form 3.3A, Form 3.3B and Form 3.4)** two (2) months before due date, to forward the reports to the primary reviewers for review and comments, to communicate with the investigators if there is need for further information or action and to submit to full board a list of progress for approval.

It is the responsibility of the primary reviewers to review the reports to check completeness of information and ensure that the data are in accordance with the protocols and other related documents approved by the IRB. In cases that the original

primary reviewers are no longer a member of the IRB, the Chair will be asked to do the review of the progress report.

3.5.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Monitor and remind the principal investigators to submit progress reports or annual report two months before the due date **(Form 3.3A and Form 3.3B)**	Secretariat	1 working day
2	Receive and check for the completeness of information in the progress report submitted. Give acknowledgement receipt. Forward document to Member secretary and Chair	Secretariat	1 working day
3	Determine if progress report will undergo SPARES/ full board review **(Form 2.6)**	Member-Secretary Chair	1 working day 1 working day
4	Forward the progress report to the primary reviewers for assessment	Secretariat	1 working day
5	Review the progress report if it is in accordance with the approved protocol and related documents. Assess the post approval monitoring parameters and recommend renewal of approval if appropriate. Submit report to secretariat.	Primary reviewers	1 working day
6	Collate the comments of the primary reviewers and include in the full board meeting agenda	Secretariat	1 working day
7	Present summary of the progress report due for submission for the month and the recommendations of the primary reviewers during the full board meeting. Discuss and make a decision on the renewal of approval and schedule of next renewal	Chair IRB Members	1 working day
8	Communicate IRB decision to Principal Investigator **(Form 2.9C)**	Secretariat	1 working day
9	File the Progress Report in Active File and transfer the Protocol folder and status of those who fail to submit as an inactive file	Secretariat	1 working day

10	Update the database, protocol index and tracker	Secretariat	1 working day

Detailed Instructions

3.5.4.1 Secretariat checks the database and tracks due dates of progress reports of Protocols approved by the Makati Medical Center IRB.

Secretariat prepares and sends reminder letter/notice addressed to the principal investigator two months before the due date of the expiration of approval.

State that the progress report should be submitted 1 month before the expiration of approval to give time for the assessment and decision to renew approval.

Failure to submit progress report prior to the validity of approval would end the approval and would render the protocol inactive.

3.5.4.2 Principal investigator submits the progress or annual report **(Form 3.3A and Form 3.3B)** within one month or 30 days before the date of expiry of approval.

Secretariat receives the progress report, reviews the completeness of submitted report based on the items in Progress Report **(Form 3.3A and Form 3.11)** and provides acknowledgement receipt.

Secretariat checks the following:

A. The GCP training of the Principal Investigator and all key persons are current (within the last three years).
B. ALL REQUIRED DOCUMENTS MUST BE submitted ONE (1) MONTH prior to the expiration date.
   - Progress/ Annual Report signed by original Investigator.
   - current consent/ assent form (applicable), with tracked changes. To highlight the changes, the revisions should be in **bold** and <u>underlined</u>.
   - summary of all approved amendments/ revisions since the last renewal
   - summary of protocol deviations/violations and corrective preventive measures
   - summary of the adverse events for onsite and offsite with causality analysis from the principal investigator and from the sponsor. Indicate whether the event is part of the investigator brochure
   - summary of site visit report (if any)

- a copy of each previously submitted Progress Report, if applicable.
- The letter of intent addressed to the IRB Chair specifies the reason for renewal of approval.

Progress reports expiring within the month are included in the agenda of the full board meeting for continuing review based on progress report and decision of renewal of the approval. Date of next renewal period is likewise decided upon during the full board meeting.

Secretariat forwards the Progress report to the Member secretary and Chair for the determination of the type of review.

3.5.4.3 Member-secretary recommends the type of review and the Chair approves if the progress/ annual report will undergo Expedited or Full board review (Form 2.6).

(NB. The full board for continuing review for a study previously approved under full board review and SPARES for continuing review for research that qualified for expedited review.)

3.5.4.4 Secretariat distributes the progress report to the primary reviewers who conducted the initial review of the involved study protocol for assessment, evaluation and recommendation on the renewal of approval and next renewal period,

3.5.4.5 Primary reviewers conduct continuing review of the progress report and documents submitted to check if they are in accordance with the protocol and related documents which were approved by the IRB using F**orm no. 3.3A and 3.3B**

In the review of the Progress the following are the key evaluation points **(Form 3.3B)**:

1) Risk Assessment
   a. The risks to the subjects are minimized
   b. The risks to the subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be expected to result.
2) Adequacy of Informed Consent
   a. Informed consent/ Assent forms current (most recent)
   b. Appropriate, new significant findings since the last continuing review that may be related to the subjects' willingness to continue participation provided to enrolled subjects (e.g., important toxicity or adverse event information)
3) Local Issues

a. Changes in the investigator's situation or qualifications (e.g., suspension of hospital privileges, medical license; involvement in numerous clinical trials)
b. Evaluation, investigation and resolution of complaints related to the research
c. Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and regulations, applicable state and local law, or standards of professional conduct of practice.
d. Report from third party observation of the research (including the informed consent process) carried out
e. Investigator concerns about trial conduct at the local site (e.g., study coordinator ineffectiveness, inability of subjects to understand sections of the informed consent document required by institutional policies).

4) Trial Progress
   a. Study start data and expected duration
   b. Total subject enrollment (onsite and other sites)
      1. Expected enrollment rate
      2. Actual enrollment rate
      3. Reason for the difference between the expected and actual enrolment rate
      4. Enrollment issues
   c. Subject withdrawal
      1. Number of subjects who withdrew
      2. Summary of reasons for withdrawal at local site
   d. Amendments
      1. Amendment
      2. Date of Approval
   e. SAEs
      1. Brief description of SAE report
      2. Outcome
      3. Date Reported to IRB
   f. Protocol Deviations
      1. Brief description of Protocol Deviation
      2. Corrective Action Taken
      3. Date Reported to IRB

The IRB may also request the Principal Investigator to provide additional information.

Primary reviewers may request verification from sources other than the Principal Investigator when:

1) The IRB has concerns about information provided by the principal investigator.

2) There is conflicting information between investigator provided materials and knowledge obtained by the IRB.
3) Non-compliance with Continuing Review requirements.
4) Concerns expressed by research participants, employees, sponsor, regulatory agencies, and/or a member or the general public.
5) Complex projects involving unusual levels or types of risk to subjects.
6) Concerns about possible material changes without IRB approval.

Primary reviewers recommend approval of the progress report if there is no deviation or violation of IRB approval.

If there is any deviation or violation of approvals given by the IRB, the primary reviewers recommend that appropriate action to be taken by the principal investigator (e.g. amendment of the protocol or consent form, etc. for progress reports; explanation of deviation or violation for final reports, etc.)

The primary reviewer must complete the review within 1 working day and submit complete accomplished evaluation form 3.3B to Secretariat prior to next full board meeting

3.5.4.6 Secretariat collates the comments of the primary reviewers and finalizes the agenda.

A. List of protocols which are due for renewal of approval is included in the agenda and presented during the full board meeting
B. Summary of the submitted progress report of each protocol is presented during the full board meeting
C. Decision on the progress report and continuing review to renew the approval is finalized during the full board meeting
D. The IRB file, including relevant IRB meeting minutes, should be made available to IRB members prior to the meeting at which continuing review will be conducted to allow members to resolve any questions that may arise.

3.5.4.7 Recommendations by the primary reviewers about the progress report is presented to the board meeting by the Chair.

Summary of the progress of the research, any significant issues and recommendations are presented. Critical issues pertinent to the decision of renewal are discussed and considered,

Board Decision

The board determines the need for the investigator to elaborate, explain or clarify any aspect of the progress as deemed necessary. The following are the possible IRB decisions for progress reports **(Form 2.9C)** and application for renewal of approval:

A. Renew approval with no further action, Date of next renewal: _____
B. Approval pending:
   1) Request additional information
   2) Recommend modification
C. Recommend suspension of:
   1) enrollment of new subjects
   2) research procedures in currently enrolled subjects
   3) the entire study
D. Termination of approval
E. Others

For studies that are approved to continue, the notification states the date when approval is effective, the period of time for which the study is approved, the next renewal of approval date and any conditions of re-approval.

For studies that did submit progress report and application for renewal until after the current expiration date, it will be considered inactive. The new expiration date is from the date of the convened meeting at which IRB approval of the renewal application is granted.

Lapses of IRB Approval

A. If the IRB has not reviewed and approved a research project by the end of the approval period specific by the IRB, the study will be considered in non-compliance. The IRB approval automatically expires and the protocol is considered inactive.
B. The investigator will be notified of expiration of approval in writing within a week of the expiration date.
C. Continuation of research interventions or interactions in previously enrolled subjects should only continue if the safety of the patient is at stake.
D. A request to continue research interventions or interactions with previously accrued subjects after the expiration date must be submitted in writing to the IRB **(Form 3.9)**.
E. The IRB will document **(Form 3.3A)** why the lapse in approval occurred and identify any steps that need to be taken to prevent future lapses in approval.
F. If there is a pattern of non-compliance with the requirements for continuing review, the IRB will determine the appropriate corrective actions and may be grounds for suspension or termination **(Form 3.10)**.

G. The IRB duly notifies the sponsor of any instance of serious or continuing non-compliance with IRB requirements.

3.5.4.8 Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes **(Form 4.2)** and communicates **(Form 2.9C)** the board decision to the principal investigator. The date of next renewal is indicated on the Notice of Decision.

3.5.4.9 Secretariat keeps a copy in the protocol files of the progress report signed by the Primary Reviewers and the Chair or Member-Secretary.

For protocols with renewed approval, the progress report is filed in the protocol folder and it remains to be in the Active file.

Protocols with no renewed approval prior to validity of the current approval shall be transferred to the inactive files and archived accordingly. It may be transferred to active file again when there is a renewal application and justification on why progress report was not submitted on time. And only after the board has decided to renew the application and consider the protocol active again.

3.5.4.10 Database, protocol index and document tracker **(Form 4.4A and Form 4.4B)** are updated.

3.6 Final Report

3.6.1 Purpose

To describe the IRB review procedures for final reports.

3.6.2 Scope

This SOP also aims to provide instructions for the review of final reports that are submitted by the Principal Investigator after completion of subject enrollment and all follow up procedures.

3.6.3 Responsibility

It is the responsibility of the Principal Investigator to submit a Final report after completion of the approved study protocol.

Process Flow

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive the final report after completion of subject enrollment and all follow up procedures **(Form 3.4).** Check for completeness and provide acknowledgement receipt	Secretariat	1 working day
2	Forward the final report to the primary reviewers and include in agenda of next full board meeting	Secretariat	1 working day
3	Review the final report and submit evaluation form to secretariat	Primary reviewers	1 working day
4	Discuss and acknowledge the final report during the IRB full board meeting.	Primary reviewers/ Chair	1 working day
5	Communicate IRB decision to Principal Investigator **(Form 2.9B)**	Secretariat	1 working day
6	File the Final Report in the protocol folder and transfer folder to the Inactive Files cabinet	Secretariat	1 working day
7	Update the database, tracker and index.	Secretariat	1 working day

Detailed Instructions

3.6.4.1 Secretariat receives the Final Report **(Form 3.4)** once the study has been completed and checks for the completeness of the final report as follows:

a. Letter of Intent addressed to the IRB Chair specifying the date the study was initiated and the date it was completed.
b. Final Report Form **(Form 3.4)**
c. Final paper, for investigator-initiated protocols only.

3.6.4.2 Secretariat forwards the final report to the primary reviewers and includes the protocol in the agenda of the next full board meeting

3.6.4.3 Primary reviewers evaluate the final report and gives recommendation using the final report **(Form 2.9B)** and submits to the Secretariat. In cases that the original primary reviewers are no longer a member of the IRB, the Chair will be asked to do the review of the final report.

3.6.4.4 During the full board meeting, primary reviewers and IRB Chair acknowledges the final report

The following are the possible IRB decisions for final reports **(Form 2.9B)**:

A. Acknowledged
B. Request further information
C. Recommend further action
D. Others

IRB acknowledges the Final Report and considers the study completed **(Form 2.9B)**

3.6.4.5 Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates the board decision to the principal investigator.

3.6.4.6 Secretariat keeps a copy of the final report in the protocol file signed by the Primary Reviewers and the Chair or Member-Secretary.

Secretariat marks the folder of the completed protocol and archives the entire study protocol accordingly. Completeness of protocol is through the index prior to archiving to inactive files.

Completed protocol is archived in the inactive file for three (3) years.

3.6.4.7 Database, index and document tracker **(Form 4.4A and Form 4.4B)** are updated.

3.7 Patient's Requests/Queries

3.7.1 Purpose

To describe the IRB procedures related to participant requests and queries.

3.7.2 Scope

This SOP applies to all queries and requests related to the rights and well-being of the research participants in studies approved by the Makati Medical Center IRB.

3.7.3 Responsibility

A designated member of the secretariat is responsible for receiving participant queries and requests related to their participation, refers relevant issues to the IRB Chair or members for the IRB to take appropriate action. The Secretariat keeps records of all action taken by the IRB.

3.7.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive and document the request or query **(Form 3.6)** Acknowledge receipt. Forward query or request to Member secretary ⬇	Secretariat	1 working day
2	Assess the nature of the request and refer to the appropriate person ⬇	Member Secretary	1 working day
3	Take action and refer to full board if necessary ⬇	Member Secretary Chair	1 working day
4	Communicate the decision to the person who made the query **(Form 2.9G)** ⬇	Secretariat	1 working day
5	File the documents in protocol folder, update database, index and tracker	Secretariat	1 working day

Detailed Instructions

3.7.4.1 Receive the request or query.

A. The Makati Medical Center IRB secretariat receives the inquiry or requests from research participants/patients or the community through various forms of communication (email, telephone call, letter, walk-in etc.)
B. For telephone requests, requestor is asked to formalize request through email, letter or through website.

3.7.4.2 Secretariat the nature of the request and refer to the Member secretary for guidance

3.7.4.3 Take action

A. Reply to the request or query, if it is within the authority of the Secretariat or refer to the Chair or IRB member for appropriate action.
B. A designated IRB member takes appropriate action.
    1) Investigate the fact.
    2) Record information and any action or follow-up taken in the **Form 3.6**
    3) Sign and date the form and forward to the Secretariat for filing.
    4) Report to the Makati Medical Center IRB about the action taken and the outcomes.

3.7.4.4 Secretariat communicates the decision to the person who made the query **(Form 2.9G)**.

3.7.4.5 Secretariat records the request and information in the request record form (Form 3.6) and keep a copy in the files.

A. Keep the record form in the "response" file.
B. Keep a copy in the protocol folder
C. Store the file in the appropriately labeled shelf

Secretariat updates the database, index and tracker accordingly

3.8 Early Protocol Termination or Withdrawal

3.8.1 Purpose

To describe the IRB procedures related to early termination or withdrawal of protocol implementation.

3.8.2 Scope

This procedure describes how the IRB proceeds and manages the premature or early termination or withdrawal of a protocol when subject enrollment is discontinued before the scheduled end of the study. Protocols are usually terminated at the recommendation of the Data Safety Monitoring Board (DSMB), the Scientific Director, sponsor, principal investigator, by the IRB itself or other authorized bodies.

3.8.3 Responsibility

It is the responsibility of the IRB to act on any early protocol termination application. It is also the responsibility of the IRB to withdraw approval for any previously approved protocol when the safety or benefit of the study participants is doubtful or at risk. All applications are reviewed at full board for appropriate action.

The Secretariat is responsible for the receipt and management of the termination documentation. The primary reviewers review the reasons for early termination and make a recommendation to full board.

3.8.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive the application or recommendation for early termination utilizing the Study Termination Form **(Form 3.8)**. Acknowledge receipt of the document ⬇	Secretariat	1 working day
2	Check approval given by the IRB from the protocol files and collect relevant information. Forward report and document to the Primary reviewer. Include in the agenda of the next full board meeting ⬇	Secretariat	1 working day

3	Review the termination package or termination issues and make recommendations. Submit the evaluation form to Secretariat	Primary reviewers	1 working day
4	Discuss at full board for the appropriate decision.	Members	1 working day
5	Communicate the board decision to the principal investigator utilizing the Notification of IRB Decision Form **(Form 2.9)**.	Secretariat	1 working day
6	File copies of the documents to the protocol folder. Transfer the folder to the inactive files and update database, index and tracker.	Secretariat	1 working day

Detailed Instructions

3.8.4.1 Receive application or recommendation for early study termination/ withdrawal. . Acknowledge receipt.

A. Receive recommendation and comments from the Sponsor, DSMB, IRB members, Scientific Director, or other authorized bodies for study protocol termination.
B. Inform the principal investigator to prepare and submit a protocol termination package.
C. Receive the study protocol termination package prepared and submitted by the principal investigator.
D. Check the completeness of the contents of the package to include the Study Termination **(Form 3.8)**
E. The request for termination memorandum should contain a brief written summary of the protocol, its results, accrual data and the actions of the investigator on the management of participants still enrolled in the study after termination. Reason for termination is specified.

3.8.4.2 Check approval given by the IRB from the protocol files and collect relevant information. Forward report and documents to Primary reviewers.

Secretariat include the protocol termination/withdrawal notice in the next full board meeting.

3.8.4.3 Primary Reviewers review the termination package safety data or termination issues and make recommendation. It is important for the termination package to contain a plan to follow up the participants who are still active in the study. Evaluation Form is submitted to Secretariat

3.8.4.4 Discuss at full board for appropriate decision:

A. Acknowledged
B. Request Additional Information
C. Request Meeting with the Principal Investigator
D. Others

3.8.4.5 Communicate the IRB decision utilizing the Notification of IRB Decision Form **(Form 2.9)**.

3.8.4.6 Keep the files in protocol folder and archive in inactive files.

Inactive files are archived three (3) years.

Update IRB database, protocol index **(Form 4.5)** and tracker **(Form 4.4A and 4.4B)** accordingly.

3.9 Non-Compliance to MMC IRB Administrative Protocols

3.9.1 Purpose

To describe the IRB process of erring investigators who fail to comply with the procedures set by Makati Medical Center Institutional Review Board (MMC IRB)

3.9.2 Scope

This SOP applies to all MMC-affiliated investigators with protocols conducted in and outside Makati Medical Center (MMC). This specifies appropriate actions to ensure compliance.

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.

3.9.3 Responsibility

It is the responsibility of the IRB Secretariat to monitor compliance to MMC Standard Operating Procedures and Protocol
It is the responsibility or the board members or designated members to take action related to non compliance to MMC Protocol
It is responsibility of the MMC IRB is to ensure all investigators comply with MMC IRB administrative protocols

3.9.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Monitor or receive report of non-compliance with the MMC IRB SOP. Forward the concern to the Member-Secretary and Chair ⬇	Secretariat	1 working day
2	Review noncompliance report and determine the urgency and appropriate action ⬇	Member Secretary/ Chair	1 working day
3	Discuss at full board and make a decision.	Members/ Chair	1 working day

4	Notify the investigator of the decision	Secretariat/ Chair	1 working day
5	Keep records in protocol folder and update the database, index and tracker	Secretariat	1 working day
6	Follow up the recommended action after a reasonable time.	Secretariat	1 working day

Detailed instructions

3.9.4.1 Secretariat monitors compliance or any IRB member may receive noncompliance reports **(Form 3.5)**. The Secretariat receives the report of non-compliance with the MMC IRB SOP and ensures the completeness of the information.

3.9.4.2 Noncompliance report is forwarded to the Member Secretary and Chair for appropriate assessment of the urgency of the concern and action needed.

3.9.4.3 Issues as well as the details of non-compliance involving research investigators are included in the agenda of the IRB meeting for Board recommendation and decision.

Criteria for Non-Compliance

If a non-registered study has been completed, the following sanction/s will be imposed:

A. For the 1st offense:
   1) Prohibition from citing MMC as the study location or institutional review center.
   2) Non-inclusion of the study in the investigator's list of reference or bibliography.

B. For the next offense:
   - Prohibition from participation of the investigator(s) in any other institutional research in MMC.

Criteria for Withdrawal of Approval

Approval may be withdrawn by the MMC IRB for the following reasons:

A. Breach of previously approved conduct of the research.
B. Failure to respond to MMC IRB's request for information/ action.

Board Decision

A. Continue study and monitor compliance
B. Request for further information
C. For site visit
D. Suspend the study*
E. Suspend enrollment of new patients*
(NB. until the following are met:*
1) Additional information is made available.
2) MMC IRB recommendations are implemented by the Principal Investigator and considered satisfactory by the MMC IRB.)
F. Terminate approval of current study**
*(NB** Termination is based on one or more of the following:*
1) SAE reports that indicate significant and study related harm to participants
2) Fraudulent violations and major breach of previously approved protocols that affects scientific integrity and safety of participants
3) Implementation of major amendments with implications to participant safety and scientific integrity without approval by the MMC IRB
4) Failure to respond to MMC IRB's request for information/action

Research proposal of an involved Principal Investigator or co-investigator are held in abeyance as determined by the Chair.

Principal investigator may be invited during the full board meeting for clarification about the issue.

For reports of non-compliance to the SOP, the chair is informed of such report and calls for a special meeting when needed to deliberate on the incident.

Board members discuss and recommend the appropriate sanction. The Chair gives the final decision of the board.

3.9.4.4 Notification of the Makati Medical Center IRB's decision
For the non-compliance report, the Secretariat prepares a letter to inform the investigator of the decision. The chair signs the notification.

3.9.4.5 Non-compliance records are filed and the IRB database, tracker and index are updated accordingly.

3.9.4.6 Secretariat follows up the action after a reasonable time as stipulated in the letter to the principal investigator.

MMC IRB SOP Version 8
Document History (Chapter 3)

Author	Chapter	Version	Date	Summary of Changes
Darwin A. Dasig, M.D.	3	6	November 17, 2020	• Added Section 3.4 Review of RNE Reports
Hazel Docuyanan, RPh, MS	3	7	April 01, 2021	• Defined the specific turn-around time in the process flow. • Included pertinent details in the detailed instructions of the process flow • Removed the RNE • Separated the noncompliance to MMC IRB administrative protocols • Included the review of member secretary and chair to determine the type of review for post approval reports (expedited or full board) for all post approval submissions • Included additional information (SAEs, Amendments and Protocol Deviations) to be provided by Principal Investigator/Research Team during submission of progress report/ renewal of approval. • Defined minor and major amendments and its relation to appropriate channel for review. • Defined protocol deviation/ violations and non-compliance and classify into minor (deviation) and major (violation) types.

Hazel Docuyanan, RPh, MS	3	8	June 09, 2021	• Major and minor deviations are classified accordingly. • In cases that the original primary reviewers are no longer a member of the IRB, the post-approval reports will be reviewed by the Chair. • The forms are revised to indicate only the contact numbers and email address of the IRB Secretariat Staff to ensure that in case of resignation or changes, there will be no need to change the whole form.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

NOTIFICATION OF IRB DECISION - PROTOCOL DEVIATION / VIOLATION (Form 2.9A)

TO THE IRB SECRETARIAT: *ENCODE THE NECESSARY INFORMATION. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

This is to inform you of the IRB decision related to your application for review of the following documents:

Date of Submission (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s)** (if any)	Click here to enter text.
Protocol Title	Click here to enter text.		
Date of Initial Approval of Protocol (MMM/DD/YYYY)	Click here to enter text.		
Protocol Deviation(s) Reported and Action Taken	Click here to enter text.		

Type of Review			
☐ Expedited	☐ Full board	☐ SJREB	**Date of Meeting:** (MMM/DD/YYYY)

The following are the issues or concerns raised by the Board. Details of the action required from the investigator:
Click here to enter text.

IRB DECISION	☐ Continue study and monitor compliance ☐ Request for further information ☐ For site visit ☐ Amend protocol ☐ Amend Informed Consent Form ☐ Suspend the study* *(NB.* until the following are met:* *1. Additional information is made available.* *2. MMC IRB recommendations are implemented by the Principal Investigator and considered satisfactory by the MMC IRB.)* ☐ Terminate approval of current study *(NB** Termination is based on one or more of the following:* *1) SAE reports that indicate significant and study related harm to participants* *2) Fraudulent violations and major breach of previously approved protocols that affects scientific integrity and safety of participants* *3) Implementation of major amendments with implications to participant safety and scientific integrity without approval by the MMC IRB*

	4) *Failure to respond to MMC IRB's request for information/action*

Name of IRB Chair	Signature	Date (MMM/DD/YYYY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

NOTIFICATION OF IRB DECISION - FINAL REPORT (Form 2.9B)

TO THE IRB SECRETARIAT: *ENCODE THE NECESSARY INFORMATION. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

This is to inform you of the IRB decision related to your application for review of the following documents:

Date (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s) (if any)**	Click here to enter text.
Protocol Title	Click here to enter text.		
Date of Initial Approval of Protocol (MMM/DD/YYYY)	Click here to enter text.		
Date of Submission of Final Protocol (MMM/DD/YYYY)	Click here to enter text.		

Other Document(s) Filed:

Click here to enter text.

Type of Review

☐ Expedited ☐ Full board ☐ SJREB **Date of Meeting:** (MMM/DD/YYYY)

IRB Decision

☐ Acknowledged

☐ Request for further information:

☐ Recommend further action

☐ Others_____

Name of IRB Chair	**Signature**	**Date** (MMM/DD/YYYY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

NOTIFICATION OF IRB DECISION - PROGRESS REPORT (Form 2.9C)

TO THE IRB SECRETARIAT: *ENCODE ALL THE INFORMATION REQUIRED IN THE SPACE PROVIDED. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

This is to inform you of the IRB decision related to your progress report:

Date of Submission (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s)** (if any)	Click here to enter text.
Protocol Title	Click here to enter text.		
Date of Initial Approval of Protocol (MMM/DD/YYYY)	Click here to enter text.		
Date of Submission of Progress Report (MMM/DD/YYYY)	Click here to enter text.		
Date of Submission of Last Progress Report (MMM/DD/YYYY)	Click here to enter text.		

Type of Review

☐ Expedited ☐ Full board ☐ SJREB **Date of Meeting:** (MMM/DD/YYYY)

IRB Decision

☐ Renew approval with no further action

Duration of Approval Period: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ to _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Deadline of next progress report: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

☐ Approval pending

- ☐ Request additional information:
- ☐ Recommend modification

☐ Recommend suspension of:

- ☐ Enrolment of new subjects
- ☐ Research procedures in currently enrolled subjects
- ☐ The entire study

☐ Termination of approval

☐ Others (specify):

Name of IRB Chair	Signature	Date (MMM/DD/YYYY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

NOTIFICATION OF IRB DECISION - SITE VISIT REPORT (Form 2.9D)

TO THE IRB SECRETARIAT: *ENCODE ALL THE INFORMATION REQUIRED IN THE SPACE PROVIDED. SHADE THE APPROPRIATE BOX.*

This is to inform you of the IRB decision related to Site Visit conducted by MMC-IRB.

Date of Submission (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s) (if any)**	Click here to enter text.
Protocol Title	Click here to enter text.		
Date of Initial Approval of Protocol (MMM/DD/YYYY)	Click here to enter text.		
Date of Submission of Site Visit (MMM/DD/YYYY)	Click here to enter text.		
Date of IRB Meeting Site Visit was Reported (MMM/DD/YYYY)	Click here to enter text.		

Type of Review

☐ Expedited ☐ Full board ☐ SJREB **Date of Meeting:** (MMM/DD/YYYY)

IRB Decision

- ☐ Continue study and post approval monitoring
- ☐ Amend the protocol
- ☐ Amend the Informed Consent form
- ☐ Stop recruitment
- ☐ Terminate the study
- ☐ Blacklist Principal Investigator/ Sponsor
- ☐ Recommend other corrective measures (specify): _
- ☐ Others (specify): _

Name of IRB Chair	Signature	Date (MMM/DD/YYYY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

NOTIFICATION OF IRB DECISION - SERIOUS ADVERSE EVENT REPORT (Form 2.9E)

TO THE IRB SECRETARIAT: *ENCODE ALL THE INFORMATION REQUIRED IN THE SPACE PROVIDED. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

This is to inform you of the IRB decision related to your report of Serious Adverse Events.

Date of Submission (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s) (if any)**	Click here to enter text.
Protocol Title	Click here to enter text.		
Date of Initial Approval of Protocol (MMM/DD/YYYY)	Click here to enter text.		
Date of Serious Adverse Event Report (MMM/DD/YYYY)	Click here to enter text.		
Term of the Adverse Event Report	Click here to enter text.		
Date of IRB Meeting SAE was Reported (MMM/DD/YYYY)	Click here to enter text.		

IRB Decision

- ☐ Request an amendment to the: ☐ Protocol ☐ Consent Form
- ☐ Request further information:
- ☐ Suspension of:
  - ☐ Enrollment of new research participants until further review of the IRB
  - ☐ A trial-related procedures (except those intended for safety and well-being of the participant) until further review by the IRB
- ☐ Termination of the study
- ☐ Take note and continue monitoring
- ☐ Site Visit

Name of IRB Chair	Signature	Date (MMM/DD/YYYY)

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

NOTIFICATION OF IRB DECISION - EARLY STUDY TERMINATION (Form 2.9F)

TO THE IRB SECRETARIAT: *ENCODE ALL THE INFORMATION REQUIRED IN THE SPACE PROVIDED. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

This is to inform you of the IRB decision related to your Notice of Early Study Termination.

Date of Submission (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s) (if any)**	Click here to enter text.
Protocol Title	Click here to enter text.		
Date of Initial Approval of Protocol (MMM/DD/YYYY)	Click here to enter text.		
Date of Submission of Early Study Termination (MMM/DD/YYYY)	Click here to enter text.		
Reason for Early Study Termination	Click here to enter text.		
Type of Review	☐ Full Board ☐ Expedited (SPARES) ☐ Expedited (SJREB) Date of Meeting (MMM/DD/YYYY):		

IRB Decision
☐ Acknowledged
☐ Request additional information
☐ Request meeting with the principal investigator
☐ Others:

Name of IRB Chair	**Signature**	**Date** (MMM/DD/YYYY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

NOTIFICATION OF IRB DECISION - PARTICIPANT'S REQUEST/ QUERY (Form 2.9G)

TO THE IRB SECRETARIAT: *ENCODE ALL THE INFORMATION REQUIRED IN THE SPACE PROVIDED.*

This is to inform you of the IRB decision related to your request/ query:

Date (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.

Name of the Participant	Click here to enter text.
Contact Information of the Participant	Click here to enter text.
Title of the Participating Study	Click here to enter text.
Participant's Request	Click here to enter text.
Action Taken and IRB Decision	Click here to enter text.

Type of Review			
☐ Expedited	☐ Full board	☐ SJREB	**Date of Meeting:** (MMM/DD/YYYY)

Name of IRB Chair	**Signature**	**Date** (MMM/DD/YYYY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

CERTIFICATE OF APPROVAL

Protocol Title	
Protocol Version No. and Date	
Principal Investigator	
Co-Investigator	

Date of Initial Submission (MMM/DD/YYYY)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol No.**	

List of Documents Approved:

Other Document(s) Filed:

Type of Review	☐ Full Board ☐ Expedited/SPARES ☐ Expedited/SJREB
	Date of Initial Review (MMM/DD/YYYY):
Duration of Approval Period	
Frequency of Progress Report	
Date of Resubmission (MMM/DD/YYYY)	

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

The Makati Medical Center Institutional Review Board (MMC IRB) strictly adheres to the provisions of the Declaration of Helsinki and the International Conference on Harmonization-Good Clinical Practices (ICH-GCP). All MMC IRB members participated in the review of the study. The decision of approval was arrived at by consensus. Please refer to the attached Post-Approval Guidelines.

Noted by:

Name of IRB Chair	Signature	Date (MMM/DD/YYYY)

Recipient's Name	Signature	Date (MMM/DD/YYYY)

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

APPROVAL LETTER (AMENDMENTS)
(Form 2.10A)

This is to certify that the following protocol and related documents have been granted approval by the Makati Medical Center IRB for implementation.

Date (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s)** **(if any)**	Click here to enter text.
Protocol Title	Click here to enter text.		
Date of Initial Approval of Protocol (MMM/DD/YYYY)	Click here to enter text.		
Date of Submission of the Amendment(s) (MMM/DD/YYYY)	Click here to enter text.		

List of Documents Approved:

Click here to enter text.

Other Document(s) Filed:

Click here to enter text.

Summary of Changes:

Amendment	Reason
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.

Type of Review	☐ Full Board ☐ Expedited (SPARES) ☐ SJREB
	Date of Initial Review (MMM/DD/YYYY):
Date of Approval	Click here to enter text.

The Makati Medical Center Institutional Review Board (MMC IRB) strictly adheres to the provisions of the Declaration of Helsinki and the International Conference on Harmonization-Good Clinical Practices (ICH-GCP). All MMC IRB members participated in the review of the study. The decision of approval was arrived at by consensus. Please refer to the attached Post-Approval Guidelines.

Name of IRB Chair	Signature	Date (MMM/DD/YYYY)

Recipient's Name	Signature	Date (MMM/DD/YYYY)

MMC-IRB Serious Adverse Event Report Form 3.1-A

Please use GOOGLE CHROME instead of INTERNET EXPLORER.

For ONSITE SAEs, kindly fill out all information needed. Please forward nine (9) printed copies of this from to IRB office after encoding. Please submit the ONSITE SAEs within seven (7) days after recognition of events.

For OFF SITE SAEs, kindly fill out the ff information only:
1.Date of Onset
2. Event
3. Suspect drug
4. Relationship
5. Country
6. Type of report (E.g. Initial, follow-up, SUSAR listing)
For OFF SITE SAEs, there is no need to print out this form. Instead, kindly forward two (1) printed copy of the original report to the IRB office after encoding.You may submit the OFFSITE SAEs together with the progress report.

Ensure accuracy and right click to print before submitting.

* Required

MMC Protocol Number *

This is a required question

Sponsor Protocol Number *

Protocol Title *

Principal Investigator *
Full name (Surname, First Name, Middle Initial)

Patient Initials
(First, Last)

Date of Birth

mm/dd/yyyy

Age

Gender

Weight (Kg)

Diagnosis/Diagnoses

Country

If Philippines, is it in Makati Medical Center? *

Reaction Onset

Specify the date when the event/reaction occured

mm/dd/yyyy

Describe Reaction(s) including relevant tests/lab data *

Narrate the reaction in detail (e.g. relevant tests, lab data, location of event, interventions given, etc.)

Adverse Event Term *

Identify the event that occurred.

Case Description
Elaborate on the adverse event that occured.

Treatment
Details on the treatment/medication given, if any. Specify dose and duration.

Outcome
Specify the condition of the patient after the treatment was given.

Seriousness *
(Check all appropriate)

- Patient died
- Involved or prolonged in-patient hospitalization
- Involved persistent or significant disability or incapacity
- Life threatening
- Results in congenital anomaly or birth defect
- Other:

Is it an expected reaction?
Based on approved drug information

Causal Relationship (Investigator Reporter) *
Causal Relationship as perceived by the Investigator Reporter

Causal Relationship (Sponsor) *
Causal Relationship as perceived by the Sponsor

Causal Relationship (MMC Investigator) *
Causal Relationship as perceived by the MMC Investigator

Suspect Drug/s (Include generic name) *
Include the name of drug and dose being given.

Daily Dose

Route(s) of administration

- Oral
- Sublingual
- Intravenous
- Intramuscular
- Subcutaneous
- Topical
- Inhalation
- Other:

Indication for use

Therapy date of the Suspect Drug (from)
Specify date the drug was started
mm/dd/yyyy

Was the drug stopped?

- No
- Yes

If YES, Therapy date of the Suspect Drug (to)
Specify date the drug was stopped
mm/dd/yyyy

Did the reaction abate after stopping the drug?

Did the reaction reappear after reintroduction of the same drug? *

Concomitant Drug/s (exclude those used to treat reaction)
Other drug/s being given aside from the study drug. Include inclusive dates. Indicate if none.

Concomitant conditions
Specify other conditions of the patient (e.g. Diagnosis, Allergies, Pregnancy with last menstrual period, etc.) and inclusive dates. Indicate if none.

Other relevant History (e.g. Diagnosis, Allergies, Pregnancy)
Include inclusive dates. Indicate if none. Check below if Unknown.

Unknown

Name of Manufacturer

Address of Manufacturer

Control Number of Manufacturer
Indicate if unknown

Date Received by Manufacturer

mm/dd/yyyy

Report Source

- Study
- Health Professional
- Literature
- Other:

Date Reported

mm/dd/yyyy

Report Type

Remarks

Name of Reporter *

Address of Reporter *

Signature of Investigator (For printed copy)

Submit

Never submit passwords through Google Forms.

100%: You made it.

INSTITUTIONAL REVIEW BOARD

SERIOUS ADVERSE EVENT REPORT
REVIEWER'S RECOMMENDATION FORM
(Form 3.1B) ONSITE REPORT

TO THE SECRETARIAT: *ATTACH THIS FORM TO FORM 3.1A BEFORE DISTRIBUTING TO THE REVIEWERS, SAE SUBCOMMITTEE CHAIR AND SAE SUBCOMMITTEE MEMBERS.*

TO THE SAE SUBCOMMITTEE CHAIR OR MEMBER: *PUT A (√) MARK ON THE APPROPRAITE TICK BOX. INDICATE THE NEEDED INFORMATION ON THE SPACE PROVIDED, IF APPLICABLE. PRINT NAME, SIGN AND DATE THIS FORM. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

Date of Submission of Report (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.

Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.

Principal Investigator	Click here to enter text.	**Co-investigator(s)** **(if any)**	Click here to enter text.

Protocol Title	Click here to enter text.

Recommendation

☐ Request an amendment to the: ☐ Protocol ☐ Consent Form

☐ Request further information _

☐ Suspension of:

- ☐ Enrolment of new research participants until further review of the IRB
- ☐ A trial-related procedures (except those intended for safety and well-being of the participant) until further review by the IRB

☐ Termination of the study

☐ Take note and continue monitoring

☐ Site Visit

Name of SAE Subcommittee Chair/ Member	Signature	Date (MMM/DD/YYYY)

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

PROTOCOL AMENDMENT REVIEW
(Form 3.2)

TO THE PRINCIPAL INVESTIGATOR: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Date of Submission (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s)** (if any)	Click here to enter text.
Principal Investigator's Contact Number	Click here to enter text.	**Principal Signature**	Click here to enter text.
Date of Initial Approval of Protocol (MMM/DD/YYYY)	Click here to enter text.		
Protocol Title	Click here to enter text.		

TO THE PRINCIPAL INVESTIGATOR: *ON THE FIRST COLUMN, SPECIFY THE AMENDMENTS FOR APPROVAL. PROVIDE A COMPARISON BETWEEN THE ORIGINALLY APPROVED VERSION AND THE NEW VERSION FOR APPROVAL. ON THE SECOND COLUMN, SPECIFY THE REASON FOR THE AMENDMENT. YOU MAY ADD MORE ROWS OR EXTRA PAGES, AS NEEDED.*

TO THE REVIEWER/ INDEPENDENT CONSULTANT: *IF THE AMENDMENT IS APPROVED, PUT A (√) CHECK MARK ON THE THIRD COLUMN. KINDLY STIPULATE ON THE FOURTH COLUMN YOUR COMMENTS OR OTHER CLARIFICATIONS, IF NEEDED. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

List of Amendments (*originally approved version versus the new version)*		**Reason**	**Primary Reviewers only**	
Original Version	**New Version**		**Approval**	**For Review** ***(Specify comments.)***
1.				
2.				
3.				
4.				
5.				

TO THE REVIEWER/ INDEPENDENT CONSULTANT: *PRINT NAME, SIGN AND DATE THIS FORM. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

Type of Review
☐ Expedited ☐ Full board **Date of Meeting Presented:** _ Click here to enter text. ____ (MMM/DD/YYYY)

Primary Reviewer's Recommendation

☐ Approval

☐ Minor Modification:

Summary of Revisions: Click here to enter text.

☐ Major Modification:

Summary of Revisions: Click here to enter text.

☐ Disapproval

Reason: Click here to enter text.

☐ Pending Decision

Reason: Click here to enter text.

Name of Primary Reviewer	Signature	Date (MMM/DD/YYYY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

**If IRB approval of your study has expired, you must also complete the Expired Study Report Form.*
**If you plan on closing your study, do not complete this form. Please complete the Final Study Report/Study Closure Form.*

TO THE PRINCIPAL INVESTIGATOR: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION. CLEARLY TYPE ALL PORTIONS OF THIS FORM. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

Date of Submission (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Protocol Title	Click here to enter text.		
Expiration Date of Study Approval (MMM/DD/YYYY)	Click here to enter text.		
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.		
Department	Click here to enter text.		

Telephone Number	Mobile Number	Mailing Address	Email Address
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

Additional Contact: If additional information is needed, specify the contact person if other than the PI (e.g., study coordinator)	Click here to enter text.	**Email Address/ Contact Number**	Click here to enter text.

STUDY PERSONNEL

Co-Investigator(s):	Click here to enter text.
Other Study Personnel (i.e., research coordinators, data managers, etc.)	Click here to enter text.

Have there been any changes in study personnel not previously reported to the IRB? Indicate the changes below and when:
Click here to enter text.

PROTOCOL SUMMARY

Summary of Study: Attach current protocol with version date.

A. What is you research question (hypothesis?)
Click here to enter text.

B. Describe the Design
Click here to enter text.

C. What will the subjects be asked to do? What will be done to the subjects?
Click here to enter text.

D. Describe the risks to the subjects:
Click here to enter text.

E. Describe the potential benefits to subjects or others, if any:
Click here to enter text.

PROJECT STATUS (Check all that apply)

☐ **A. Active – Open to Enrolment**
☐ No enrolment to date ☐ Participant enrolment has begun ☐ Specimen collection or chart review occurring

☐ **B. Active – Closed to Enrolment**
☐ Treatment and/or active follow-up continues ☐ Long term follow-up of subjects as patients (e.g., following for survival) ☐ Data analysis only

☐ **C. Study Closed Prior to Completion**
Do not complete this form. Please complete the Final Study Report/ Study Closure Form

☐ **D. Study Completed** (***Enrolment, treatment, data collection, follow-up, and data analysis are complete.)***
Do not complete this form. Please complete the Final Study Report/ Study Closure Form.

SPONSOR/ FUNDING SOURCE

Is this research funded at this time?	☐ **No** ☐ **Yes**	
Has the sponsor/ funding source changed since the last review?	☐ **No** ☐ **Yes**	**If YES, please attach the Sponsor/ Funding Information*

DRUG AND DEVICE STUDIES

A. Since the last continuing review, has your study site been inspected by the FDA?	☐ **No** ☐ **Yes**	
If YES, did the site receive Inspectional Observations?	☐ **No** ☐ **Yes**	**If YES, please attach a copy of Inspectional Observations and your response to FDA*
B. Is the Principal Investigator the holder of the IND or IDE?	☐ **No** ☐ **Yes**	**If YES, provide a copy of the most recent IND/ IDE report submitted to the FDA.*

ENROLLMENT

Has enrolment been lower than anticipated?	☐ **No** ☐ **Yes**	**If YES, explain the reasons for low or no enrolment and, if relevant, what steps were or will be taken to increase enrolment:**	

CUMULATIVE SUMMARY OF SUBJECTS ENROLLED TO DATE

(For studies involving record and/or specimen review only, skip and complete Section B)
(For study designs utilizing multiple consent forms, this table may be replicated).

1. Number of subjects accrued	Click here to enter text.
2. Number of subjects currently active/ on study *(For example, subjects receiving study interventions/ interactions or long-term follow-up)*	Click here to enter text.
3. Number of subjects completed *(Without events leading to early termination/ withdrawal from the study)*	Click here to enter text.
4. Number of subjects who voluntarily withdrew consent after enrolling *(For example, after signing the consent form, the subject changes his/her mind and decided not to participate or to stop participating after completing some of the study procedures)*	Click here to enter text.
Explanation	Click here to enter text.
5. Number of subjects terminated/ withdrawn from the study by the investigator due to adverse event(s) *For example, subject met toxicity drop point or experienced a serious adverse event.*	Click here to enter text.
Explanation	Click here to enter text.
6. Number of subjects terminated/ withdrawn from the study by the investigator due to other reasons *For example, non-compliance with the protocol, pregnancy, etc.*	Click here to enter text.
Explanation	Click here to enter text.
7. Number of subjects lost to follow-up	Click here to enter text.
Explanation	Click here to enter text.
8. Number of subjects who are no longer participating for reasons other than those above	Click here to enter text.

Explanation	Click here to enter text.

9. Total of item nos. 2 to 8 *(should be equal to item no. 1)*	Click here to enter text.

10. Number of subjects approved at Makati Medical Center	Click here to enter text.

RECORDS AND SPECIMENS

A. Number of specimens and/or records approved by the IRB:	Click here to enter text.

B. Did you review medical records, patient charts, radiographs or other patient information for this study?	☐ **No** ☐ **Yes**	**No. of records reviewed to date:**	

C. Did you analyze specimens (e.g., archival tissue, blood, blood products, or body fluids) for this study?	☐ **No** ☐ **Yes**	**No. of specimen analyzed to date:**	

PROGRES REPORT: (Complete all sections in sufficient detail to assess current risk/ benefit)

The primary purpose of continuing review is to re-assess the risk-benefit ratio at intervals appropriate to the degree of risk associated with the study procedures, but not less than once per year. At the time of continuing review, the IRB must ensure that the regulatory criteria for IRB approval continue to be satisfied. Please answer the following questions so that both you and the IRB can determine whether any new information has emerged, either from the research itself or from other sources that could alter the IRB's previous determinations, particularly with respect to risk to subjects.

A. Unanticipated problems

1. Since the last IRB review, have any serious, unexpected adverse events occurred that were considered related to participation in the research that have not been previously reported to the IRB?	☐ **No** ☐ **Yes** **If YES, please attach Unanticipated Problem Report describing any previously unreported unanticipated event.*

2. Since the last IRB review, have any other unanticipated problems involving risks to subjects or others occurred, for example, medication or laboratory errors, loss or unintended disclosure of confidential information, investigator suspension or termination?	☐ **No** ☐ **Yes** **If YES, please attach Unanticipated Problem Report describing any previously unreported unanticipated event.*

B. PROTOCOL DEVIATIONS/ VIOLATIONS

Since the last IRB review, have any protocol deviations/ violations involving risks to subjects or others occurred that have not been previously reported to the IRB?	☐ **No** ☐ **Yes** **If YES, please attach the IRB Protocol Deviation/ Violations Report Form (Form 3.5)*

C. COMPLAINTS ABOUT THE RESEARCH

Since the last IRB review, have any subjects or others complained about the research?	☐ **No** ☐ **Yes** **If YES, please provide a summary of the complaints and how they were resolved.*

D. PROGRESS REPORT AND INTERIM FINDINGS

1. Provide a brief general summary of the progress of the study.
Click here to enter text.

2. Has there been an interim analysis or are there any interim findings to report?	☐ **No** ☐ **Yes** **If YES, please provide results of interim analysis or a summary of any findings to date.*

E. DATA AND SAFETY MONITORING

Is this a trial subject oversight by a Data Safety and Monitoring Board (DSMB), Data Monitoring Committee (DMC), other similar body (e.g., coordinating or statistical center), or group whose responsibilities include review of adverse events and interim findings?	☐ **No** ☐ **Yes** **If YES, indicate the type of monitoring plan below, and attach a copy of the most recent report or communication.* ☐ *DSMB/ DMC/ DSMC* ☐ *Monitor/ monitoring group* ☐ *Coordinating or statistical center*

F. OTHER INFORMATION RELEVANT

Since the last IRB review, have there been major advances, changes in standards or care, drug approvals, device recall, new black box warning, or key publications in major peer-reviewed journals which would alter the risk/ benefit assessment of this study?	☐ **No** ☐ **Yes** **If YES, please provide a summary of relevant information. Provide the key references and interpretation/ commentary.*

G. INVESTIGATOR'S ASSESSMENT OF RISKS AND BENEFITS

1. Since the last IRB review, have the risks to subjects changed?	☐ **No** ☐ **Yes**	**If YES, please provide a summary of the changes in the risks to subjects.*
2. Since the last IRB review, has the magnitude of benefit or likelihood of benefit to subjects changed?	☐ **No** ☐ **Yes**	**If YES, please provide a summary of the changes in the anticipated benefits.*
3. Do the risks to subjects continue to be reasonable in relation to anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonably be expected to result?	☐ **No** ☐ **Yes**	**If NO, explain below.*

H. PROPOSED MODIFICATIONS/AMENDMENTS/ CHANGES TO THE RESEARCH

Are any changes to the research being proposed at this time?	☐ **No** ☐ **Yes**	**If YES, please attach the Protocol Amendment Review Form (Form 3.2) detailing proposed changes. ***

*****NB: The IRB must approve all changes to protocols and consent forms and other study documents (e.g., questionnaires, recruitment letters, advertisements, etc.) prior to implementation.***

ATTACHMENTS:
Attach the following:

☐ **Research Protocol**: Current dated version of the protocol (Provide highlighted or strikeout copy of any changes proposed with this continuing review submission, if applicable.)

☐ **Investigator Financial & Other Personal Interests Disclosure Form** for each investigator and key study personnel

☐ **Research Consent Forms**: Copy of most recent IRB-approved consent forms showing the IRB-approval stamp

☐ **Research Consent Forms**: Consent forms for re-approval without IRB-approval stamp (if changes are proposed, include one copy with proposed changes highlighted and one copy without proposed changes highlighted).

☐ **For multi-center trials -** Please attach any relevant multi-center reports

PRINCIPAL INVESTIGATOR'S ASSURANCES

- I have followed all applicable policies and procedures of Makati Medical Center, national and local laws regarding the protection of human subjects in research, including, but not limited to, the following:
- The research was performed as approved by the IRB under the direction of the Principal Investigator

by appropriately trained and qualified personnel;

- Unanticipated problems were promptly reported to the IRB, as well as any other information necessary for appropriate oversight of the research;
- Research-related records (and source documents) will be maintained in a manner that documents the validity of the study and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;
- Study-related records will be retained and available for audit for a period of 15 years after the study has ended (or longer, according to sponsor or publication requirements) even if I leave the Makati Medical Center;
- IRB approval or exemption will be obtained before initiating any new research activities involving human subjects; and
- All co-investigators, research staff, employees, and students assisting in the conduct of the research will be informed of their obligations in meeting the above commitments.

I verify that the information provided in this Continuing Review Application is accurate and complete.

Name of the Principal Investigator	Signature	Date (MMM/DD/YYYY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

PROGRESS REPORT EVALUATION FORM
(Form 3.3B)

TO THE PRINCIPAL INVESTIGATOR: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED ON THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Date of Submission (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s)** (if any)	Click here to enter text.
Principal Investigator's Signature	Click here to enter text.	**Principal Investigator's Contact No.**	Click here to enter text.
Protocol Title	Click here to enter text.		
Date of Initial Approval of Protocol (MMM/DD/YYYY)	Click here to enter text.		

TO THE PRINCIPAL INVESTIGATOR: *INDICATE THE LOCATION OF THE ASSESSMENT POINT (E.G. PAGE NO.) IN THE SECOND COLUMN. INDICATE **N/A** IF NOT APPLICABLE*

TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT: *IF YOU HAVE NO FURTHER COMMENTS, PUT A (√) MARK ON THE SPACE PROVIDED.OTHERWISE, SPECIFY THE ISSUES IN THE SPACE PROVIDED.PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

ASSESSMENT POINT	***LOCATION***	**REVIEWER'S COMMENTS**	
		APPROVE/ SUFFICIENT/ NO FURTHER COMMENT **(put a check √ mark)**	FOR REVISION (specify issues)
1. The number of subjects accrued; (For multi-site studies, the number of subjects accrued at the local site and the number accrued study-wide, if available) a. Expected enrollment rate b. Actual enrollment rate c. Reason for the difference between the expected and actual enrolment rate d. Enrollment issues e. Number of subjects who withdrew f. Summary of reasons for withdrawal at local site	Click here to enter text.		

2. A brief summary of any amendments to the research approved by the IRB since the IRB's initial review or the last continuing review.	Click here to enter text.		
3. Any new and relevant information, published or unpublished, since the last IRB review, especially information about risks associated with the research	Click here to enter text.		
4. A summary of any unanticipated problems. In many cases, such a summary could be a brief statement that there have been no unanticipated problems (i.e., adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document and Investigator's Brochure (if applicable);	Click here to enter text.		
5. A summary of any subject withdrawals from the research since the last IRB review, and the reasons for withdrawal, if known;	Click here to enter text.		

6. A summary of any complaints about the research from subjects enrolled at the local site since the last IRB review;	Click here to enter text.		
7. The latest versions of the protocol and sample informed consent document(s) in use at the site;	Click here to enter text.		
8. Any proposed modifications to the informed consent document or protocol;	Click here to enter text.		
9. The current Investigator's Brochure, if any, including any modifications;	Click here to enter text.		

10. Any other significant information related to subject risks, such as the most recent report, if any, from data safety monitoring board (DSMBs); (Additionally, it may be useful for sponsors to ensure that IRBs are informed when DSMBs have met, even when no problems have been identified and the DSMBs has recommended continuation of the study as designed. This information can be transmitted either by the investigator or directly by the sponsor);	Click here to enter text.		
11. Aggregate information about relevant regulatory actions occurring since the last review that could affect safety and risk assessments (e.g., withdrawal or suspension from marketing in any country on the basis of safety, reports of recalls and device disposition.)	Click here to enter text.		
12. Drug Safety Update Report (DSUR) Executive Summary, if available.	Click here to enter text.		
13. Changes in the investigator's situation or qualifications (e.g., suspension of hospital privileges, medical license, involvement in numerous clinical trials, renewal of GCP training, etc.)	Click here to enter text.		

14. Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and regulations, applicable state and local law, or standards of professional conduct of practice.	Click here to enter text.		
15. Study start data and expected duration	Click here to enter text.		
16. Summary of SAEs/SUSARS For Onsite: AE reported Causality Date Reported to IRB For Offsite: AE reported Count			
17. Summary of Protocol Deviations Description of Violation Corrective Action Taken Date Reported to IRB Type of Protocol Deviation			

TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT: *PRINT NAME, SIGN AND DATE THIS FORM.PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

Reviewer's Recommendation:
☐ Renew approval with no further action ☐ Approval pending ☐ Request additional information

☐ Recommend modification

☐ Recommend suspension of:

☐ Enrolment of new subjects

☐ Research procedures in currently enrolled subjects

☐ The entire study

☐ Termination of approval

☐ Others (specify): _____

Primary Reviewer's Name	Signature	Date (MMM/DD/YYYY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

TO THE PRINCIPAL INVESTIGATOR: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

Date of Submission (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s)** (if any)	Click here to enter text.
Principal Investigator's Signature	Click here to enter text.	**Principal Investigator's Contact Number**	Click here to enter text.
Protocol Title	Click here to enter text.		
Date of Initial Approval of Protocol (MMM/DD/YYYY)	Click here to enter text.		
Study site(s):	Click here to enter text.	**No. of Study Arms**	Click here to enter text.

A. CUMULATIVE SUMMARY OF SUBJECTS ENROLLED TO DATE

(For studies involving record and/or specimen review only, skip and complete Section B)
(For study designs utilizing multiple consent forms, this table may be replicated).

1. Number of subjects accrued	Click here to enter text.
2. Number of subjects currently active/ on study *(For example, subjects receiving study interventions/ interactions or long-term follow-up)*	Click here to enter text.
3. Number of subjects completed *(Without events leading to early termination/ withdrawal from the study)*	Click here to enter text.
4. Number of subjects who voluntarily withdrew consent after enrolling *(For example, after signing the consent form, the subject changes his/her mind and decided not to participate or to stop participating after completing some of the study procedures)*	Click here to enter text.
Explanation	Click here to enter text.
5. Number of subjects terminated/ withdrawn from the study by the investigator due to adverse event(s) *For example, subject met toxicity drop point or experienced a serious adverse event.*	Click here to enter text.
Explanation	Click here to enter text.

6. Number of subjects terminated/ withdrawn from the study by the investigator due to other reasons *For example, non-compliance with the protocol, pregnancy, etc.*	Click here to enter text.
Explanation	Click here to enter text.
7. Number of subjects lost to follow-up	Click here to enter text.
Explanation	Click here to enter text.
8. Number of subjects who are no longer participating for reasons other than those above	Click here to enter text.
Explanation	Click here to enter text.
9. Total of item nos. 2 to 8 *(should be equal to item no. 1)*	Click here to enter text.
10. Number of subjects approved at Makati Medical Center	Click here to enter text.

B. RECORDS AND SPECIMENS

A. Number of specimens and/or records approved by the IRB:	Click here to enter text.		
B. Did you review medical records, patient charts, radiographs or other patient information for this study?	☐ **No** ☐ **Yes**	**No. of records reviewed to date:**	Click here to enter text.
C. Did you analyze specimens (e.g., archival tissue, blood, blood products, or body fluids) for this study?	☐ **No** ☐ **Yes**	**No. of specimen analyzed to date:**	Click here to enter text.
Duration of the Study (Date Initiated and Completed) (MMM/DD/YYYY)	Click here to enter text.		
Objectives	Click here to enter text.		

Summary of Results:
Click here to enter text.

TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT: *INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX. SPECIFY ON THE SPACE PROVIDED OTHER COMMENTS, IF APPLICABLE.*

Comments/ Recommendations of the Primary Reviewer

☐ Acknowledged

☐ Request for further information

____

☐ Recommend further action

____

☐ Others

____

Primary Reviewer's Name	Signature	Date (MMM/DD/YYYY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

Date of IRB meeting the report was presented (MMM/DD/YYYY)	Click here to enter text.

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

DEVIATION/ NON-COMPLIANCE/ VIOLATION REPORT (Form 3.5)

TO THE PRINCIPAL INVESTIGATOR: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PUT A (✓) MARK ON THE APPROPRIATE TICK BOX. PRINT, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Date of Submission (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s)** (if any)	Click here to enter text.
Principal Investigator's Signature	Click here to enter text.	**Principal Investigator's Contact Number**	Click here to enter text.
Protocol Title	Click here to enter text.		
Reported by	Click here to enter text.	**Contact Number**	Click here to enter text.

Description of Deviation/ Violation:
Click here to enter text.

Action(s) Taken	Click here to enter text.	**Date** (MMM/DD/YYYY)	Click here to enter text.

Nature of the Protocol Deviation/ Violation:	
☐ Principal Investigator Deviation from the protocol ☐ Participant Non Compliance ☐ Others: Beyond the situations	☐ Major ☐ Minor

TO THE PRIMARY REVIEWER : *PUT A (✓) MARK ON THE APPROPRIATE TICK BOX. PRINT NAME, SIGN AND DATE THIS FORM.*

IRB DECISION	☐ Continue study and monitor compliance ☐ Request for further information ☐ For site visit ☐ Amend Protocol	☐ Amend Informed Consent Form ☐ Suspend the study ☐ Terminate approval of current study

Primary Reviewer's Name	Signature	Date (MMM/DD/YYYY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

Date of IRB meeting the report was presented (MMM/DD/YYYY)	Click here to enter text.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

REQUEST/ QUERY RECORD (Form 3.6)

TO THE IRB SECRETARIAT: *ENCODE THE NECESSARY INFORMATION. PUT A (√) MARK ON THE APPROPRIATE TICK BOX.*

Type of Request
☐ Fax ☐ Mailed Letter ☐ E-mail ☐ Walk-in ☐ Others:_ _

Participant's Name	
Contact Address	
Phone Number	
Title of the Participating Study	
Starting Date of Participation	
What is/are requested	
Request forwarded to	
Action Taken	
Outcome	
Date of IRB meeting the report was presented (MMM/DD/YYYY)	

IRB Chair	**Signature**	**Date** (MMM/DD/YYYY)

SITE VISIT REPORT (Form 3.7)

TO THE IRB SECRETARIAT: *ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

IRB Protocol Number	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Co-investigator(s) (if any)**	Click here to enter text.

Principal Investigator	**Contact Number**	**Department (for residents/ fellows only)**
Click here to enter text.	Click here to enter text.	Click here to enter text.

Protocol Title	Click here to enter text.

Total number of expected subjects:	Click here to enter text.	**Total number of subjects enrolled:**	Click here to enter text.

TO BE FILLED OUT BY THE MMC IRB REPRESENTATIVE
TO THE IRB MEMBER/ REPRESENTATIVE: *PUT A (√) MARK ON THE APPROPRIATE TICK BOX.SPECIFY THE REQUIRED INFORMATION IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN IN THE SPACE PROVIDED. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

Are the site facilities appropriate?	☐ **No**	☐ **Yes**
Comment (s): Click here to enter text.		

Are the informed consents recent?	☐ **No**	☐ **Yes**
Comment (s): Click here to enter text.		

Any adverse events found?	☐ **No**	☐ **Yes**
Comment (s): Click here to enter text.		

Any protocol non-compliance/ violation?	☐ No	☐ Yes
Comment (s): Click here to enter text.		

Are all case record forms up to date?	☐ No	☐ Yes
Comment (s): Click here to enter text.		

Are storage of data and investigating products locked?	☐ No	☐ Yes
Comment (s): Click here to enter text.		

How well are participants protected?	☐ No	☐ Yes
Comment (s): Click here to enter text.		

Any outstanding tasks or results of visit?	☐ No	☐ Yes
Comment (s): Click here to enter text.		

Date of Visit (MMM/DD/YYYY)	Click here to	**Duration of Visit (hours)**	Click here to	**Time started**	Click here to	**Time Ended**	Click here to

	enter text.		enter text.		enter text.		enter text.

Name of IRB Member/ Representative/ Companion	Click here to enter text.

Date of IRB meeting the report was presented (MMM/DD/YYYY)	Click here to enter text.

IRB Decision

- ☐ Continue study and post approval monitoring
- ☐ Amend the protocol
- ☐ Amend the Informed Consent form
- ☐ Stop recruitment
- ☐ Terminate the study
- ☐ Blacklist Principal Investigator/ Sponsor
- ☐ Recommend other corrective measures (specify): _____ _____
- ☐ Others (specify): _____ _____

Reason for Decision

Click here to enter text.

Completed by: (signature over printed name)	Click here to enter text.	**Date** (MMM/DD/YYYY)	Click here to enter text.

Name of IRB Chair	**Signature**	**Date** (MMM/DD/YYYY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

EARLY STUDY TERMINATION (Form 3.8)

TO THE PRINCIPAL INVESTIGATOR: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Date of Submission (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text. Click here to enter text.	**Co-investigator(s)** (if any)	Click here to enter text.
Principal Investigator's Signature	Click here to enter text.	**Principal Investigator's Contact Number**	Click here to enter text.
Protocol Title	Click here to enter text.		
Date of Last Progress Report (MMM/DD/YYYY)	Click here to enter text.	**Starting Date of Recruitment** (MMM/DD/YYYY)	Click here to enter text.
Termination Date (MMM/DD/YYYY)	Click here to enter text.	**Date of Last Recruitment** (MMM/DD/YYYY)	Click here to enter text.
Target Number of Participants	Click here to enter text.	**Actual Number Enrolled**	Click here to enter text.

Reason for Termination:
Click here to enter text.

Actions of the Investigator on the Management of Participants still enrolled in the study after termination	☐ Informed the participants of the termination ☐ Study Drug was made available to the participants after the termination ☐ Follow up the participants who are still active in the study	☐ Others:

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD
TO BE FILLED OUT BY IRB

TO THE PRIMARY REVIEWER: *PRINT YOUR NAME, SIGN AND DATE THIS FORM. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

IRB Decision
☐ Approval with no further action ☐ Request additional information ☐ Request meeting with the principal investigator ☐ Others:

Primary Reviewer's Name	**Signature**	**Date** (MMM/DD/YYYY)
Click here to enter text.	Click here to enter text.	Click here to enter text.

Date of IRB meeting the report was presented (MMM/DD/YYYY)	Click here to enter text.

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

EXPIRED STUDY REPORT (Form 3.9)

TO THE PRINCIPAL INVESTIGATOR: TYPE *CLEARLY ALL PORTIONS OF THIS FORM. SPECIFY YOUR ANSWER IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM. INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX.*

Date of Submission (MMM/DD/YYYY)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s)** (if any)	Click here to enter text.
Protocol Title	Click here to enter text.		
Date of Initial Approval of Protocol (MMM/DD/YYYY)	Click here to enter text.		
Were any subjects enrolled after the expiration date?	☐ **No** ☐ **Yes**		
Were any research activities (study visits, chart reviews, data analysis using subject identifiable data, etc.) conducted after the expiration date?	☐ **No** ☐ **Yes**	**If YES, provide a description of these activities:**	

Provide an explanation why a timely Continuing Review Application (Form 3.3A) was not submitted prior to the expiration date:
Click here to enter text.

Provide a corrective action plan describing how this can be prevented from occurring in the future:
Click here to enter text.

Principal Investigator's Name	**Signature**	**Date** (MMM/DD/YYYY)
Click here to enter text.		Click here to enter text.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

REQUEST FOR CLOSURE OF EXPIRED PROTOCOL (Form 3.10)

IRB approval expires automatically when continuing review of a study protocol does not occur prior to the end of the approval period specified by the IRB. Enrollment of new subjects/study related activities cannot occur after the expiration of IRB approval. In order for the IRB to determine whether they can approve your request for closure the following information is required.

TO THE PRINCIPAL INVESTIGATOR: *CLEARLY TYPE ALL PORTIONS OF THIS FORM. SPECIFY YOUR ANSWER IN THE SPACE PROVIDED. PRINT, SIGN AND DATE THIS FORM.*

Date of Submission (MMM/DD/YYYY)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol Number**	
Principal Investigator		**Co-investigator(s)** (if any)	
Protocol Title			
Date of Initial Approval of Protocol (MMM/DD/YYYY)			
Have you been previously suspended on this or any other study?	☐ **No** ☐ **Yes**		
Were any subjects enrolled or did any research activities (study visits, chart reviews, data analysis using identifiable data, etc.) occur after the expiration date?	☐ **No** ☐ **Yes**	**If YES, provide a description of these activities:**	

Provide an explanation why a timely Request for Closure was not submitted prior to the expiration date:

Provide a corrective action plan describing how this can be prevented from occurring in the future:

Principal Investigator's Name	**Signature**	**Date** (MMM/DD/YYYY)