Chapter IV : Documentation and Archiving	Document Code: **IRB-SOP-1120-DAA-004-08**	
	Effective Date:	Page: Page 1 of 23
Issued by: **Institutional Review Board**	Approved by: *(original document signed)* **SATURNINO P. JAVIER, M.D.** **(Medical Director)**	
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Authored by:	MMC IRB SOP Team (adapted from DOH SOP)
Effective Date:	June 28, 2021
Approved by:	**D. DARWIN A. DASIG, M.D., Chair, MMC IRB**
Approval Date:	June 15, 2021

***Review: This Standard Operating Procedure is reviewed every three (3) years or earlier as indicated.**

4.1 Preparation and Distribution of Meeting Agenda

4.1.1 Purpose

To describe procedures for the preparation and distribution of the IRB meeting agenda.

4.1.2 Scope

This SOP provides instructions related to the preparation of the IRB meeting agenda and its distribution to inform IRB members and other interested individuals about the items for discussion during a full board meeting.

4.1.3 Responsibility

It is the responsibility of IRB Secretariat, under the supervision of the Secretary-Member, to compile all documents/ information submitted to the IRB within a given period to include them in the next full board meeting agenda **(Form 4.1)** for discussion or information of the IRB members.

4.1.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Collect all documents submitted to the IRB within a given period to prepare the full board meeting agenda ⬇	Secretariat/Member -Secretary
2	Have agenda approved by the Chair **(Form 4.1)** ⬇	Secretariat, Chair
3	Distribute notice of meeting and agenda to IRB members and interested parties ⬇	Secretariat
4	Communicate with the members to check if they can attend the meeting to ensure quorum ⬇	Secretariat
5	File the notice of meeting and agenda	Secretariat

Detailed Instructions

4.1.4.1 Collect all documents submitted to the IRB within a given period and put them in the full board meeting agenda for discussion or information of the IRB members.

4.1.4.2 Member-secretary reviews the prepared agenda while the Chair approves the notice of meeting or agenda.

Standard notice of meeting or agenda **(Form 4.1)** contains the following:

A. Date of preparation
B. Date, time and venue of meeting
C. Business Arising
    1) Inactivated Files/ No progress report submitted
    2) Further Information Requests
D. Agenda items
    1) Protocol Review
        a. Initial review
        b. Resubmission review
    2) Approved protocols
        a. SPARES/ expedited initial review
        b. SPARES/ expedited resubmissions
        c. SJREB Initial review
        d. SJREB resubmissions
    3) Post approval monitoring
        a. Amended protocols
        b. Safety reports
        c. Protocol deviations and violations
        d. Site visit reports
        e. Progress reports and Renewal of Approval Requests
        f. Final reports
        g. Early study termination
        h. Queries or complaints
    4) Other matters
        a. Communications
        b. Financial report

4.1.4.3 Recommendations on protocols requiring clarifications from the Principal Investigator during an IRB full board meeting are made by Makati Medical Center IRB primary reviewers, who request the Secretariat to inform the investigators about the meeting schedule. The time slot for their appearance at the IRB meeting is communicated to them. The Secretariat informs and consults the Chair about the agenda items **(Form 4.1)**. The Secretariat arranges the venue and other logistics for the meeting at least one (1) week before the scheduled meeting prior to preparation of the notice of meeting. The Secretariat makes copies of the notice of meeting containing the approved agenda to the Makati Medical Center-IRB members, at least one (1) week before the meeting.

4.1.4.4 Secretariat communicates with the IRB members to confirm their attendance and ensure quorum during the next board meeting.

4.1.4.5 Secretariat files a copy of the agenda in the Agenda and Minutes folder. Agenda document is a permanent file.

4.2 Preparation of Meeting Minutes

4.2.1 Purpose

To describe procedures for the preparation and approval of the minutes of the IRB full board meeting.

4.2.2 Scope

This SOP provides instructions related to the preparation of the IRB full board meeting minutes and its approval by the IRB members.

4.2.3 Responsibility

It is the responsibility of IRB Secretariat, under the supervision of the Member-Secretary, to document the conduct of the full board meeting, including the issues discussed, the decisions and recommendations made in accordance with the items in the IRB meeting agenda.

4.2.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Organize and document the meeting procedures and the items taken up based on the meeting agenda **(Form 4.1)** ↓	Secretariat
2	Prepare draft of Minutes **(Form 4.2)** ↓	Secretariat, Member-Secretary
3	Approve the Minutes ↓	Member-Secretary, Chair
4	File the approved Minutes	Secretariat

Detailed Instructions

4.2.4.1 Secretariat uses **Form 4.2** as a template to organize the meeting discussion in preparation to writing the minutes ahead of the meeting date.
Secretariat documents the proceedings of the meeting as the meeting progresses by writing directly into the template prepared.

Secretariat reviews the proceedings prepared during the meeting and verifies that it contains the following sections **(Form 4.2)**:

A. Date and venue of meeting
B. Member attendance (members present and absent) to determine quorum
C. Guests and observer attendance
D. Time when the meeting was called to order
E. Presiding officer
F. Conflict of interest declaration by IRB members
G. Discussion of items based on the Meeting Agenda
H. Decisions, summary of points and recommendations arrived at during the meeting
I. Name and signature of person who prepared the Minutes
J. Name and signature of the Chair with the date of approval
K. Time when the meeting was adjourned

Opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members, unless in the case of administrative or operational queries from members who require follow-up information or action.

4.2.4.2 The Secretariat submits a complete draft of the minutes to the Member-Secretary within one (1) working day after the meeting for corrections, and submits the corrected draft to the Chair for approval.

4.2.4.3 The Member-Secretary and Chair approve the minutes of the meeting (**Form 4.2)**

The Secretariat uses the information in the minutes to communicate full board IRB decisions to the respective Principal Investigators.

The minutes of the IRB full board meeting, once they are finalized, are sent to the members for comments or correction. The minutes are formally approved during the next full board meeting. The minutes for the Subcommittee PAnels for Minimal Risk REsearch ProtocolS (SPARES) meeting are not required to be approved by the full board.

4.2.4.4 The Secretariat files the signed minutes in the Minutes of the Meeting folder of the IRB. Minutes of the meeting are a permanent file.

4.3 Preparation of Communication Records

4.3.1 Purpose

To describe the preparation of IRB communication records and the filing of such records.

4.3.2 Scope

This SOP provides instructions related to the preparation of IRB communication to various parties and the management of such files.

4.3.3 Responsibility

It is the responsibility of IRB Secretariat, under the supervision of the Member-Secretary, to document all communication made by the IRB secretariat to different parties that deal with the IRB.

4.3.4 Process Flow/Steps

No.	Activity	Responsibility
1	Organize all communications received and issued by the IRB	Secretariat
2	Record the details of the communication	Secretariat
3	Update protocol document tracker	Secretariat
4	File communication documents	Secretariat

Detailed Instructions

4.3.4.1 IRB communications refer to documented communications and can be in the form of hard copy letters or emails. It is encouraged that all IRB communications, received and issued, are in this form to facilitate documentation of all actions, instructions, and even responses to queries. IRB Secretariat organizes a log of communications which also function as a log of submissions if the communication comes with a submission.

IRB communication folder is organized into two (2) sections – outgoing and incoming communications, filed per year. All communication documents are permanent and must be kept confidential.

4.3.4.2 Log of protocol submissions should have at least the following elements:

A. Date of communication/submission
B. Name of IRB party contacted
C. Study information, i.e., sponsor, protocol number, principal investigator, etc.
D. Content of communication or submission
E. Notation of any follow-up necessary
F. Type of submission (if communication refers to a submission)
G. Contact information (address, telephone number, and e-mail) of sending party
H. Name and signature of individual who received the communication and completed the record

4.3.4.3 Protocol document tracker **(Form 4.4A and 4.4B)** is updated accordingly.

4.3.4.4 A copy of the communication/submission is filed in the:

A. Protocol file folder
B. IRB Communications folder
C. Others, as appropriate

4.4 Management of Active Study Files, Documents and Records

4.4.1 Purpose

To describe the IRB procedures related to the management of active study files, documents and records.

4.4.2 Scope

This SOP provides instructions related to the management of active study files originating from protocol submissions and includes all documents that reflect all actions taken by the IRB before completion of the study. It also provides instructions for the maintenance and storage of other IRB documents and records.

4.4.3 Responsibility

It is the responsibility of IRB Secretariat, under the supervision of the Secretary-Member, to manage all protocol submissions and all documents that reflect all IRB actions and organize them into orderly files that are kept at the IRB office.

The Secretariat also manages the maintenance and storage of all relevant IRB documents and records.

4.4.4 Process Flow/Steps

No.	Activity	Responsibility
1	Collect all protocol files submitted for review ⬇	Secretariat
2	Design a standard coding system for all protocols submitted to the IRB for review ⬇	MMC IRB
3	File all submitted documents in a protocol folder and chronologically organize the contents of the active study files according to time of receipt ⬇	Secretariat
4	Check study file folder for completeness ⬇	Secretariat
5	Update the active protocol files regularly and keep the files in the office ⬇	Secretariat

6	Ensure that all actions are recorded in the database	Secretariat

Detailed Instructions

4.4.4.1 Makati Medical Center IRB-approved protocols are considered active from the moment the protocol files are received for review until such time they are inactivated (completed, withdrawn or terminated). Active files are either ongoing review or ongoing study.

Protocol Classification

Active				
Classification	**Description**	**Criteria for qualification**	**Label color code**	**Label coding**
Ongoing review	Protocols submitted for review and approval by IRB	Application form (Form 2.1)	Yellow	Standard coding
Ongoing study	Protocols that have been approved by IRB	Approval letter (Form 2.10)	Green	Standard coding

4.4.4.2 Protocol Label Code Format

A. It is necessary to use a unique identifier or code to refer to this file for efficient file management. Code active study files as follows: MMCIRB (year)-number (chronological number based on order of receipt). For example, if Protocol entitled "First Clinical Drug Trial on Pediatric Patients" is the first protocol received in 2012, the code MMCIRB 2012-001 is the code that should be used to identify this protocol.
B. Coding of protocol numbering YYYY – XXX
   1) YYYY – year the protocol was submitted
   2) XXX – chronological number for the year
C. Additional Tag
   1) Exempted Protocol – Add EXEMPT on the code format and counting is chronological per year
      Example: MMCIRB 2021 – 001 EXEMPT
   2) SJREB Protocols– Add SJREB Code to the MMC-IRB Code; must be reflected on all protocol files

Example: MMCIRB 2021 – 001/SJREB 2021-01

4.4.4.3 Protocol Folders

A. Protocol documents are filed in sturdy file folders, using one (1) folder per study protocol title.
B. The folders are kept in secured well-identified locked cabinets.
   - Keys to locked cabinets are kept by assigned staff.
C. File folders are labeled using the code of the study file.

4.4.4.4 Protocol Folder Contents

Study file folder contains the following documents and should have protocol index:

A. All versions of study protocol
B. Related documents that came with the study protocol
C. Principal investigator and co-investigators' CVs and other similar documents
D. Reviewers' assessment forms
E. Amendment reports
F. Continuing review/Approval Renewal applications
G. Serious Adverse Event Reports or Safety Notifications (Onsite/Offsite)
H. Non-compliance (Deviation or Violation) reports
I. Participant Queries
J. Site Visit Reports
K. Approval letters
L. Notifications of IRB Decision
M. Miscellaneous communication
N. Final report
O. For SJREB protocols: A copy of the SJREB meeting minutes where the protocol was discussed.

4.4.4.5 Active Protocol File Management

A. Active files, records and documents should be properly maintained and updated.
   1) Secretariat updates the study file folder and the database every week.
   2) Protocol index and document tracker is updated whenever a new document is added.

3) Secretariat ensures completeness of filling out of forms before filing.

B. Keep all active study files in a secure file cabinet, with access limited only to (personnel allowed) who will be entrusted to keep the lock and key.

C. Actives files can be accessed outside of regular protocol review in accordance with the SOP on Maintaining Confidentiality of Study Files and IRB Documents.

D. The retention period of files is mandated by the national ethical guidelines on clinical trials. The files are retained for three (3) years after completion of the research. After which, the files are disposed.

4.4.4.6 Protocol Database

A. Study file information is entered into the IRB database using its unique code.

B. Create a secure protocol database to facilitate protocol monitoring including due dates of reports and determining active protocol status.

C. The database can be paper-based (logbook locked in the active files cabinet) or electronic (password protected) and should have at least the following fields:

1) Date Submitted
2) IRB Code
3) URL Address
4) Nickname
5) Protocol No.
6) Title
7) Principal Investigator(s)
8) Sponsor
9) Sites
10) Type of Research
11) Reviewers
12) Type of Review
13) Department
14) Review decision
15) Date of Review
16) Date of Submission of Revised Protocol
17) Approval/ Disapproval Date
18) Submission of Amendments
19) Date of Review of Amended Protocol

20) Approval/ Disapproval Date of Amended Protocol
21) Status
22) Submission Date of Updated Annual Report
23) SAE Reported
24) SUSARs Reported
25) No. of Drop-outs
26) No. of Patients who completed the Trial
27) Date of Closure/ Termination of the Study
28) Reason for Closure/ Termination of Study
29) Date of Submission of Final Report
30) Others

D) Database is updated weekly under the supervision of the Member Secretary.
E) Protocol Index is updated weekly under the supervision of the Member Secretary.
F) Protocol Tracker is updated real time under the supervision of the Member Secretary.

4.5 Archiving of Inactive Study Files, Documents and Records

4.5.1 Purpose

To describe IRB procedures related to archiving of inactive study files, documents and records.

4.5.2 Scope

This SOP provides instructions to the Secretariat related to requirements for archiving completed documents after the final report or other relevant documents have been received.

4.5.3 Responsibility

It is the responsibility of IRB Secretariat, under the supervision of the Member-Secretary, to archive in an orderly manner all protocol files that have been terminated, completed, withdrawn or is no longer active. They are kept together in a designated place in the hospital where confidentiality and security of the documents can be maintained.

4.5.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Classify which protocols are for archiving. ⬇	Secretariat
2	Design a standard coding system for inactive protocols. ⬇	MMC IRB
3	Approve final report or early study termination report. ⬇	Reviewers/ Members
4	Archive studies for three (3) years after submission of final report and update protocol database regularly. ⬇	Secretariat
5	Retrieve protocol documents when needed and record protocol documents retrieval	Secretariat

Detailed Instructions

4.5.4.1 Inactive study files are classified as follows:

Inactive				
Classification	**Description**	**Criteria for qualification**	**Label color code**	**Label coding**
Unfinished review/incomplete review	Protocols for review with no resubmissions for 6 months and remained dormant and inactive	6 months inactive from the last communication form	Orange	Standard coding with YEAR at the end to indicate the year it was rendered inactive
Completed	Studies that were completed and finished and submitted a final report	Final report form 3.4	Pink	Standard coding with YEAR at the end to indicate the year it was rendered inactive
Terminated	Studies that were terminated by IRB	Form 3.8	Red	Standard coding with YEAR at the end to indicate the year it was rendered inactive
Withdrawn	Studies were withdrawn by sponsor/principal investigator	Letter from the sponsor or principal investigator stating the reason for withdrawing study	Blue	Standard coding with YEAR at the end to indicate the year it was rendered inactive

4.5.4.2 Protocol Label Code Format

A. Protocol folders are re-coded indicating the year YYYY – XXX / ZZZZ
   1) YYYY – year the protocol was submitted
   2) XXX – chronological number for the year
   3) ZZZZ – year the protocol was completed, withdrawn or terminated
B. An archive number is assigned to the protocol by adding the / (year the final report is approved) as a suffix to the original protocol code. For example if the Final Report of Protocol MMC IRB 2010-002 is approved in 2012, the archiving code is MMC IRB 2010-002/2012.

4.5.4.3 Inactive Protocol File management

A. Inactive files are identified every last month of the year or earlier for completed or terminated protocols.
B. Upon approval of the Final Report or Early Study Termination or withdrawal, the protocol is reclassified as inactive study files and the Secretariat initiates archiving procedure.
C. Secretariat reviews the completeness of contents of the protocol file using the protocol index and transfers it from the active study filing area to the designated archive area.
D. The archiving data should be entered accordingly in the protocol database.

4.5.4.4 Retention Period

Archived study files are retained for at least three (3) years (or more for some particular cases) after completion of the research or deemed inactive.

4.5.4.5 Archived Protocol Retrieval

A. Archived protocols can be retrieved within the three(3) -year archiving period in accordance with the SOP on Maintaining Confidentiality of Study Files and IRB Documents.
B. Documents retrieval is recorded accordingly.

4.6 Maintenance of Confidentiality of Study Files and MMC IRB Documents

4.6.1 Purpose

To describe Makati Medical Center Institutional Review Board (MMC IRB) procedures related to maintaining the confidentiality of the study files and other MMC IRB documents.

4.6.2 Scope

This Standard Operating Procedure (SOP) provides instructions to the Secretariat related to maintaining the confidentiality of all study files and documents.

4.6.3 Responsibility

It is the responsibility of MMC IRB Secretariat, under the supervision of the Secretary-Member, to ensure that confidentiality is maintained in the management of all study files and records.

4.6.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Classify which IRB documents are confidential ⬇	Members/ Secretariat
2	Restrict access to confidential documents ⬇	Secretariat
3	Record copies made of confidential documents ⬇	Secretariat
4	File log of copies ⬇	Secretariat
5	Dispose files according to retention period	Secretariat

Detailed Instructions

4.6.4.1 Study files submitted to the MMC IRB and related documents are considered confidential, such as:

A. Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
B. MMC IRB documents (Meeting minutes, advice, and decisions)
C. Correspondence (experts, auditors, study participants, etc.)

4.6.4.2 Access to MMC IRB confidential documents is subject to the following limitations:

A. MMC IRB members and staff with a signed *Confidentiality Agreement and Conflict of Interest Disclosure* **(Form 1.3)** can access confidential documents outside of regular protocol review access, upon request.
B. Non-members can access specific documents by submitting a formal request. The Secretariat will provide a copy of the *Confidentiality Agreement Form for Non-members Requesting for Copies of Makati Medical Center IRB Documents* **(Form 4.3)** to be accomplished by the person making the request, and signed by the Chair.
C. Regulatory authorities have full access to Makati Medical Center IRB documents provided it is within their mandate (e.g. FDA), and upon reasonable notice to make the files available signed by the recognized official of the regulatory authority (e.g. FDA Director).

4.6.4.3 Management of Confidential Files

A. Properly handle original documents and copies of IRB documents during the day-to-day operation of the IRB to protect the confidentiality of study files and related documents. Proper handling also involves proper control and care in the distribution and storage of confidential documents of the IRB.
B. Secretariat records the retrieval of Makati Medical Center IRB documents. Access to Makati Medical Center IRB documents is generally room use only, but requests to make copies can be accommodated on a case to case basis.
C. All requests for access are recorded by the Secretariat Staff in the log before copies of any documents are released.
D. Secretariat makes only the exact number of copies requested.

E. Recipient signs for the copies requested in the Makati Medical Center IRB upon receipt of the copies.
F. Access to Makati Medical Center IRB documents is generally room use only, but requests to make copies can be accommodated on a case to case basis.

4.6.4.4 Secretariat makes a record every time a document of the Makati Medical Center IRB is accessed as described above **(Form 4.3).**

- A log filed in the protocol folder is dedicated for purposes of recording access as described above, which contains the following fields of information:
  A. Study file code
  B. Date borrowed
  C. Name of borrower
  D. Signature of borrower upon retrieval
  E. Signature of Makati Medical Center IRB Secretariat upon return of document to file box
  F. Document copied
  G. Number of copies made
  H. Number of copies received

4.6.4.5 Maintenance of IRB and Administrative Documents

4.6.4.5.1 The following are the IRB and administrative files and records, frequency of updating and retention period.

NAME OF RECORD	DESCRIPTION	FREQUENCY OF UPDATING	RETENTION PERIOD
Protocols	Protocol folder, document tracker, index	Update once a new document is added	Three (3) years
Database	Protocol data	Update once new data is added	Permanent file
IRB member profile folder	Curriculum vitae, confidentiality of agreement, appointment letter, training record	Depends on years of contract	Depends on years of contract
IRB staff profile folder	Curriculum vitae, confidentiality of	Depends on years of employment	Depends on years of employment

	agreement, training record, job description		
Independent consultant profile folder	Curriculum vitae, confidentiality of agreement, appointment letter, training record	Depends on years of contract	Depends on years of contract
Communications (incoming & outgoing letters)	Approval letters, correspondence, queries	Updated immediately	Permanent file
Financial records	Review fee, honorarium, miscellaneous, receipts,	Updated immediately	Permanent file
Standard operating procedures (SOP)	Policies and forms	Once a year	Permanent file

4.6.4.5.2 Disposal of Obsolete Files

Guidelines on Shredding of Obsolete Documents

A. Shredding is done every last Friday of the month.
B. One (1) staff will be assigned for the shredding.
C. Shredding of documents is properly documented with the following information:
    1) Document
    2) Date
    3) Person responsible
    4) Approval of an authorized person
D. Obsolete documents will be shredded on the last Friday of the month, following its retention period and after verification that it has been scanned and incorporated in the database. The following documents are considered obsolete documents:
    1) Spare documents
    2) Protocols (after 3 years of retention period)
    3) IRB Member's outdated CV
    4) Any document with confidential information
E. During submission, only one copy is kept in file. The rest of the copies are returned to the principal investigator after the review of the protocol.

4.7 Protocol Document Tracker and Protocol Index

4.7.1 Purpose

To describe the tracking procedures of the Makati Medical Center Institutional Review Board using the Document Tracker Forms **(Form 4.4A and 4.4B)**.

4.7.2 Scope

Index is use to check the completeness of the protocol files and is placed in front of the protocol folder. Document tracker is used to record all protocol submissions and communication details.

4.7.3 Responsibility

The secretariat records the activities or status of the protocols using the Document Tracker Forms **(Form 4.4A and 4.4B).**

4.7.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Receives and records the protocol file and documents submitted on the protocol index ↓	Secretariat
2	Record the movements and details of communications on protocol tracker until the time when the study is completed, terminated or withdrawn ↓	Secretariat
3	Check for completeness of protocol files using protocol index	Secretariat

Detailed Instructions

4.7.4.1 Secretariat records all protocol files on the protocol index

4.7.4.2 The Document Tracker Forms **(Form 4.4A and 4.4B)** are used to record the activities or status of a protocol. Document Tracker Forms **(Form 4.4A and 4.4B)** contains:

A. Title of the document
B. Name of Recipient and Date Received

C. Name of the person submitting/ forwarding the document and date.
D. Name of the person who returns the documents and date.

4.7.4.3 Protocol index is updated regularly to ensure completeness of all protocol documents.

MMC IRB SOP Version 8
Document History (Chapter 4)

Author	Chapter	Version	Date	Summary of Changes
Darwin A. Dasig, M.D.	4	6	November 17, 2020	• Updated the version to Version 6
Hazel Faye R. Docuyanan, RPh, MS	4	7	April 01, 2021	• Updated the version to Version 7 • Added coding for exempted protocols. • Added coding for SJREB protocols. • Added Letter O under protocol file contents to include SJREB minutes in the protocol files for SJREB protocols. • Revised retention period to three (3) years as per NEGHHR 2017 and PHREB recommendations.
Hazel Faye R. Docuyanan, RPh, MS	4	8	June 09, 2021	• Revised Minutes of the Meeting Form 4.2

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD
7th Floor Keyland Center (MMC Tower 3)
143 Dela Rosa cor. Adelantado Sts. Legaspi Village, Makati City
8888-999 Local 7166, 3972 and 3973

AGENDA OF THE MEETING

NOTICE OF MEETING

TO: Makati Medical Center Institutional Review Board Members

<Name of IRB Member>
<Name of IRB Member>
<Name of IRB Member>
<Name of IRB Member>
<Name of IRB Member>
<Name of IRB Member>
<Name of IRB Member>
<Name of IRB Member>
<Name of IRB Member>
<Name of IRB Member>
<Name of IRB Member>
<Name of IRB Member>

DATE OF MEETING: (MMM/DD/YYYY)
TIME OF MEETING: (00:00H -00:00H)
VENUE OF MEETING:

1. **CALL TO ORDER**
2. **DETERMINATION OF QUORUM**
3. **DISCLOSURE OF CONFLICT OF INTEREST (COI)**
4. **APPROVAL OF THE AGENDA OF THE MEETING**
5. **REVIEW AND APPROVAL OF THE MINUTES FROM THE PREVIOUS MEETING**
6. **BUSINESS ARISING FROM THE MINUTES**

Category	IRB Protocol No., Title and Principal Investigator	Open item	Date of release Notice of IRB Decision	Status
Initial Submission				
Resubmission				
Amendment				
Safety Report				
Protocol Deviations/Violations				
Site Visit				
Progress Report				
Updates/ Notifications				
Final Report				

Early Study Termination				
Communications: Queries or Complaints				

7. SJREB- approved Protocols

7.1.1

IRB Protocol No/SJREB Protocol No.	
Research Protocol Submission Date	(MMM/DD/YYYY)
Research Protocol Title	
Principal Investigator	
Sponsor/CRO	
Primary Reviewers	
Type of Review	
Conflict of Interest	
Date of SJREB Approval	
Review of Site-Specific Issues	**Technical/Scientific Review** **a. Title:** **b. Objective:** **c. Literature Review:** **d. Research Design** **e. Sampling Design, sample size or Number of subjects to be enrolled:** **f. Statistical/Data Analysis Plan:** **g. Methodology:** **h. Control Arm:** **i. Standard Therapy** **j. Inclusion Criteria:** **k. Exclusion criteria:**

	l. Withdrawal or Discontinuation Criteria: **m. Specimen Handling** **n. Duration:** **o. Principal Investigator's Qualification:** **p. Specimen Handling:** **q. Principal Investigator's Qualifications:** **r. Duration:** **s. Recruitment:** **Ethical Review** **a. Conflict of interest:** **b. Privacy and confidentiality:** **c. Informed consent process:** **d. Assent:** **e. Vulnerability:** **f. Risks (Level Risk, Types of Risk, Source of Risk):** **g. Compensation:** **h. Benefits (Direct Benefit to Participants, Benefits to Society/Social Value):** **i. Community consideration:** **j. Participant's follow-up and management of the study:** **k. Provision for monitoring and auditing the conduct of the research, including constitution of data safety monitoring board (DSMC):** **Informed Consent Assessment Points** **a. Explicit statement that procedures are primarily intended for research** **b. Identification of people responsible and the procedure of obtaining consent** **c. Consistency of information found in the protocol and consent form** **d. Clarity of Language used** **e. Local translation (local language/dialect)** **f. Justification of inclusion of participants who cannot consent (if applicable)** **g. Availability of different types of consent (assent, Legally Authorized Representative)** **h. Names and contact numbers of research team and the IRB** **i. Privacy and Confidentiality** **j. Inducement** **k. Provisions for medical/psychosocial support** **l. Compensation** **m. Consent Process for Emergency Situations**

<table>
<tr><td></td><td colspan="2">n. Adequacy of available information for participants
o. Continuing Informed Consent Process
p. Provisions for receiving and responding to participants'/representatives' queries
q. Statement on voluntary participation and process of withdrawal
r. Indemnity and Insurance</td></tr>
<tr><td>Decision Points for the Protocol (Site-Specific)</td><td>☐ Approved
☐ Minor Modifications
☐ Major Modifications</td><td>☐ Disapproved
☐ Pending Decision</td></tr>
<tr><td>Decision Points for the Informed Consent Form (Site-Specific)</td><td>☐ Approved
☐ Minor Modifications
☐ Major Modifications</td><td>☐ Disapproved
☐ Pending Decision</td></tr>
<tr><td>Reason for Decision</td><td colspan="2"><Total Number of Voters/Quorum> <Decision Point> of the protocol was recommended. The following issues are needed to be addressed among others:

Technical/Scientific Issues
1. <Issue to be addressed>
2. <Issue to be addressed>
3. <Issue to be addressed>

Ethical Issues
1. <Issue to be addressed>
2. <Issue to be addressed>
3. <Issue to be addressed>

<Total Number of Voters/Quorum of Full Board> <Decision Point> of the Informed Consent Form was recommended. The following issues are needed to be addressed among others:
1. <Issue to be addressed>
2. <Issue to be addressed>
3. <Issue to be addressed></td></tr>
</table>

8. PROTOCOL REVIEW

8.1. Initial Review

8.1.1. <**IRB Protocol No.> <Title>** by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert)
Type of Review: <type of review>
Time Allotment: 20 mins
Date of Submission: (MMM/DD/YYYY)

8.2. Review of Resubmission

8.2.1. <**IRB Protocol No.> <Title>** by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert)
Type of Review: <type of review>
Time Allotment: 20 mins
Date of Submission: (MMM/DD/YYYY)

9. APPROVALS FROM THE PREVIOUS MONTH

9.1. Approved Protocols in Full Board

9.1.1. <**IRB Protocol No.> <Title>** by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert) '
Type of Review: <type of review>
Turnaround time: < _ days>
Date of Initial Submission: (MMM/DD/YYY)
Date of Approval: (MMM/DD/YYYY)
Frequency of Continuing Review/Date of next review: Annually/ (MMM/DD/YYYY)

9.2. Approved Protocols in Expedited/SPARES

9.2.1. <**IRB Protocol No.> <Title>** by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert) '
Type of Review: <type of review>
Turnaround time: < _ days>
Date of Initial Submission: (MMM/DD/YYY)
Date of Approval: (MMM/DD/YYYY)

Frequency of Continuing Review/Date of next review: Annually/ (MMM/DD/YYYY)

9.3. Approved Amendments

9.3.1. <**IRB Protocol No.> <Title>** by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert) '
Type of Review: <type of review>
Date of Submission of Amendment: (MMM/DD/YYY)
Date of Approval of Amendment: (MMM/DD/YYYY)
List of Amended Documents:

10. POST APPROVAL MONITORING

10.1. Protocol Amendments for Review and Approval

10.1.1. <**IRB Protocol No.> <Title>** by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert) '
Date of Submission of Amendment: (MMM/DD/YYY)
Type of Review: <type of review>
List of Amendments:

Original Version	New Version	Reason

10.2. Safety Reports

10.2.1. **IRB Protocol No.> <Title>** by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert)
SAE Subcommittee Members: <name of reviewer>/.<name of reviewer>/<name of reviewer>
Type of Review: <type of review>
Date of Initial Approval: (MMM/DD/YYY)
Date of Submission of Safety Report: (MMM/DD/YYY)
Reported Event:
Description:
Seriousness:
Causal Relationship (as perceived by the MMC Investigator):
Causal Relationship (as perceived by the sponsor):
Recommendations:

10.3. Protocol Deviations/Violations

10.3.1. IRB Protocol No.> <Title> by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert)
Type of Review: <type of review>
Date of Initial Approval: (MMM/DD/YYY)
Date of Submission of Protocol Deviation/Violation: (MMM/DD/YYY)
Description of Deviation(s)/ Violation(s):
Action(s) Taken:

10.4. Site Visit

10.4.1. IRB Protocol No.> <Title> by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert)
Type of Review: <type of review>
Date of Initial Approval: (MMM/DD/YYY)
Date of Site Visit: (MMM/DD/YYY)
Name of IRB Representatives: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert)
Duration of Visit (hours): (00:00H – 00:00H)

10.5. Progress Report

10.5.1. Request for Renewal of Approval

10.5.1.1. IRB Protocol No.> <Title> by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert)
Type of Review: <type of review>
Date of Last Approval: (MMM/DD/YYY)
Date of Submission of Progress Report: (MMM/DD/YYY)
Reason for Renewal:

Annual Summary Report:

Number of subjects screened	
Number of subjects accrued	
Number of subjects completed	
Number of subjects who voluntarily withdrew consent after enrolling	
Number of subjects terminated/ withdrawn from the study by the investigator due to other reasons	
Summary of Amendments	***1.*** ***<Brief Description of Amendment>*** ***<Document version>*** ***<Date of IRB Approval>*** ***2.*** ***<Brief Description of Amendment>*** ***<Document version>*** ***<Date of IRB Approval>***
Summary of SAEs/SUSARS	***For Onsite:*** ***1.*** ***<AE reported>*** ***<Causality>*** ***<Date Reported to IRB>*** ***For Offsite:*** ***1.*** ***<AE reported >*** ***<Count>***
Summary of Protocol Deviations/Violations	***1.*** ***<Description of Protocol Deviation>*** ***<Corrective Action Taken>*** ***<Date Reported to IRB>*** ***<Type of Protocol Deviation>*** ***2.*** ***<Description of Protocol Deviation>*** ***<Corrective Action Taken>*** ***<Date Reported to IRB>*** ***<Type of Protocol Deviation>***

Protocol Version No. and Date	
Informed Consent Version No. and Date	
Other pertinent documents (Please specify document) Version No. and Date	

10.5.2. Due for Renewal but No Progress Report Submitted

IRB Protocol No., Title and Principal Investigator	Date of Last Renewal	Date sent of Progress Report submission reminder

10.6. Updates/Notifications

10.6.1. IRB Protocol No.> <Title> by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert)
Type of Review: <type of review>
Date of Initial Approval: (MMM/DD/YYY)
Date of Submission of Notification: (MMM/DD/YYY)
Notification:

10.7. Final Report

10.7.1. IRB Protocol No.> <Title> by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert)
Type of Review: <type of review>
Date of Initial Approval: (MMM/DD/YYY)
Date of Submission of Final Report: (MMM/DD/YYY)
Summary of Results:

10.8. Early Study Termination

10.8.1. IRB Protocol No.> <Title> by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert)
Type of Review: <type of review>

Date of Initial Approval: (MMM/DD/YYY)
Date of Submission of Early Study Termination: (MMM/DD/YYY)
Reason for Termination:

10.9. Communications: Queries/Complaints

10.9.1. IRB Protocol No.> <Title> by <Name of Principal Investigator>
Sponsor: <Name of Sponsor>
Primary Reviewers: <name of reviewer>/.<name of reviewer>/<name of reviewer> (expert)
Type of Review: <type of review>
Date received: (MMM/DD/YYY)
Queries/Complaints:

11. List of Exempted Protocols

IRB Code and Title	Principal Investigator	Date of Submission	Reason for Exemption
		(MMM/DD/YYYY)	

11. Financial Reports
11.1. Clinical Trial Agreement (CTA)
11.2. Financial Summary

12. Other Matters

Prepared by:

<Signature above Printed Name of IRB Assistant>
<Designation>

Date (MMM/DD/YYYY)

Reviewed by:

<Signature above Printed Name of Member-Secretary>
<Designation>

Date (MMM/DD/YYYY)

Approved by:

<Signature above Printed Name of Chair>
<Designation>

Date (MMM/DD/YYYY)

Date: (MMM/DD/YYYY)		
Venue:		
Members Present:	**Members Absent**:	**Independent Consultants:**
<Name of IRB Member>	<Name of IRB Member>	<Name of Independent Consultant>
	IRB Secretariat Staff:	**Others Present:**
	<Name of IRB Assistant>	<Name of Principal Investigator/Co-Investigator>
	<Name of IRB Assistant>	
	<Name of Administrative Staff>	
	<Name of Administrative Staff>	

1. CALL TO ORDER

<Name of IRB Chair> called this meeting to order at am. The Invocation was led by <Name>.

2. DETERMINATION OF QUORUM

A quorum was declared with the presence of (_) permanent members and, inclusive of the presence of (_) institutional medical members and (_) non-institutional non-medical members, as confirmed by the Secretariat.

3. DISCLOSURE OF CONFLICT OF INTEREST (COI)

There was no disclosure of any conflict of interest.

4. APPROVAL OF THE AGENDA OF THE MEETING

<Name of IRB Member> moved to approve the agenda of the meeting seconded by <Name of IRB Member>**.**

5. REVIEW AND APPROVAL OF THE MINUTES OF PREVIOUS MEETING

<Name of IRB Member> moved for the approval of the modified minutes of the meeting seconded by <Name of IRB Member>.

6. BUSINESS ARISING FROM THE MINUTES

6.1. Business Arising from Protocol Review

Category	IRB Protocol No., Title and Principal Investigator	Open item	Date of release Notice of IRB Decision	Status	Board Resolution
Initial Submission					
Resubmission					
Amendment					
Safety Report					
Protocol Deviations/Violations					
Site Visit					
Progress Report					
Updates/ Notifications					
Final Report					
Early Study Termination					
Communications: Queries or Complaints					

7. SJREB- approved Protocols

7.1.1

IRB Protocol No/SJREB Protocol No.	
Research Protocol Submission Date	(MMM/DD/YYYY)
Research Protocol Title	
Principal Investigator	
Sponsor/CRO	
Primary Reviewers	
Type of Review	
Conflict of Interest	

Date of SJREB Approval	
Review of Site-Specific Issues	**Technical/Scientific Review** **a. Title:** **b. Objective:** **c. Literature Review:** **d. Research Design** **e. Sampling Design, sample size or Number of subjects to be enrolled:** **f. Statistical/Data Analysis Plan:** **g. Methodology:** **h. Control Arm:** **i. Standard Therapy** **j. Inclusion Criteria:** **k. Exclusion criteria:** **l. Withdrawal or Discontinuation Criteria:** **m. Specimen Handling** **n. Duration:** **o. Principal Investigator's Qualification:** **p. Specimen Handling:** **q. Principal Investigator's Qualifications:** **r. Duration:** **s. Recruitment:** **Ethical Review** **a. Conflict of interest:** **b. Privacy and confidentiality:** **c. Informed consent process:** **d. Assent:** **e. Vulnerability:** **f. Risks (Level Risk, Types of Risk, Source of Risk):** **g. Compensation:** **h. Benefits (Direct Benefit to Participants, Benefits to Society/Social Value):** **i. Community consideration:** **j. Participant's follow-up and management of the study:** **k. Provision for monitoring and auditing the conduct of the research, including constitution of data safety monitoring board (DSMC):** **Informed Consent Assessment Points** **a. Explicit statement that procedures are primarily intended for research** **b. Identification of people responsible and the procedure of obtaining consent** **c. Consistency of information found in the protocol and consent form** **d. Clarity of Language used** **e. Local translation (local language/dialect)**

	f. Justification of inclusion of participants who cannot consent (if applicable) **g. Availability of different types of consent (assent, Legally Authorized Representative)** **h. Names and contact numbers of research team and the IRB** **i. Privacy and Confidentiality** **j. Inducement** **k. Provisions for medical/psychosocial support** **l. Compensation** **m. Consent Process for Emergency Situations** **n. Adequacy of available information for participants** **o. Continuing Informed Consent Process** **p. Provisions for receiving and responding to participants'/representatives' queries** **q. Statement on voluntary participation and process of withdrawal** **r. Indemnity and Insurance**	
Decision Points for the Protocol (Site-Specific)	☐ **Approved** ☐ **Minor Modifications** ☐ **Major Modifications**	☐ **Disapproved** ☐ **Pending Decision**
Decision Points for the Informed Consent Form (Site-Specific)	☐ **Approved** ☐ **Minor Modifications** ☐ **Major Modifications**	☐ **Disapproved** ☐ **Pending Decision**
Reason for Decision	*<Total Number of Voters/Quorum> <Decision Point> of the protocol was recommended. The following issues are needed to be addressed among others:* **Technical/Scientific Issues** ***1.*** *<Issue to be addressed>* ***2.*** *<Issue to be addressed>* ***3.*** *<Issue to be addressed>* **Ethical Issues** ***1.*** *<Issue to be addressed>* ***2.*** *<Issue to be addressed>* ***3.*** *<Issue to be addressed>* *<Total Number of Voters/Quorum of Full Board> <Decision Point> of the Informed Consent Form was recommended. The following issues are needed to be addressed among others:* ***1.*** *<Issue to be addressed>* ***2.*** *<Issue to be addressed>* ***3.*** *<Issue to be addressed>*	

8. PROTOCOL REVIEW

8.1. Initial Review

7.1.1.

IRB Protocol No	
Research Protocol Submission Date	(MMM/DD/YYYY)
Research Protocol Title	
Principal Investigator	
Sponsor/CRO	
Primary Reviewers	
Type of Review	
Conflict of Interest	
Review	**Technical/Scientific Review** **t. Title:** **u. Objective:** **v. Literature Review:** **w. Research Design** **x. Sampling Design, sample size or Number of subjects to be enrolled:** **y. Statistical/Data Analysis Plan:** **z. Methodology:** **aa. Control Arm:** **bb. Standard Therapy** **cc. Inclusion Criteria:** **dd. Exclusion criteria:** **ee. Withdrawal or Discontinuation Criteria:** **ff. Specimen Handling** **gg. Duration:** **hh. Principal Investigator's Qualification:** **ii. Specimen Handling:** **jj. Principal Investigator's Qualifications:** **kk. Duration:** **ll. Recruitment:** **Ethical Review** **l. Conflict of interest:** **m. Privacy and confidentiality:** **n. Informed consent process:** **o. Assent:**

	p. Vulnerability: q. Risks (Level Risk, Types of Risk, Source of Risk): r. Compensation: s. Benefits (Direct Benefit to Participants, Benefits to Society/Social Value): t. Community consideration: u. Participant's follow-up and management of the study: v. Provision for monitoring and auditing the conduct of the research, including constitution of data safety monitoring board (DSMC): Informed Consent Assessment Points s. Explicit statement that procedures are primarily intended for research t. Identification of people responsible and the procedure of obtaining consent u. Consistency of information found in the protocol and consent form v. Clarity of Language used w. Local translation (local language/dialect) x. Justification of inclusion of participants who cannot consent (if applicable) y. Availability of different types of consent (assent, Legally Authorized Representative) z. Names and contact numbers of research team and the IRB aa. Privacy and Confidentiality bb. Inducement cc. Provisions for medical/psychosocial support dd. Compensation ee. Consent Process for Emergency Situations ff. Adequacy of available information for participants gg. Continuing Informed Consent Process hh. Provisions for receiving and responding to participants'/representatives' queries ii. Statement on voluntary participation and process of withdrawal jj. Indemnity and Insurance	
Decision Points for the Protocol	☐ Approved ☐ Minor Modifications ☐ Major Modifications	☐ Disapproved ☐ Pending Decision
Decision Points for the Informed Consent Form	☐ Approved ☐ Minor Modifications ☐ Major Modifications	☐ Disapproved ☐ Pending Decision

Reason for Decision	*<Total Number of Voters/Quorum> <Decision Point> of the protocol was recommended. The following issues are needed to be addressed among others:* **Technical/Scientific Issues** ***4.*** *<Issue to be addressed>* ***5.*** *<Issue to be addressed>* ***6.*** *<Issue to be addressed>* **Ethical Issues** ***4.*** *<Issue to be addressed>* ***5.*** *<Issue to be addressed>* ***6.*** *<Issue to be addressed>* *<Total Number of Voters/Quorum of Full Board> <Decision Point> of the Informed Consent Form was recommended. The following issues are needed to be addressed among others:* ***4.*** *<Issue to be addressed>* ***5.*** *<Issue to be addressed>* ***6.*** *<Issue to be addressed>*

8.2. Review of Resubmission

8.2.1.

IRB Protocol No	
Research Protocol Submission Date	(MMM/DD/YYYY)
Research Protocol Title	
Principal Investigator	
Sponsor/CRO	
Primary Reviewers	
Type of Review	
Conflict of Interest	
Assessment of the Principal Investigator's Response to Inquiries	**1.** <MMC IRB Inquiry> <Principal Investigator's response> **2.** <MMC IRB Inquiry> <Principal Investigator's response> **3.** <MMC IRB Inquiry>

	<Principal Investigator's response>	
Decision Points for the Protocol	☐ **Approved** ☐ **Minor Modifications** ☐ **Major Modifications**	☐ **Disapproved** ☐ **Pending Decision**
Decision Points for the Informed Consent Form	☐ **Approved** ☐ **Minor Modifications** ☐ **Major Modifications**	☐ **Disapproved** ☐ **Pending Decision**
Duration of approval date	Until: **(MMM/DD/YYYY)**	
Frequency of continuing review	Annually	
Reason for Decision	***<Total Number of Voters/Quorum> <Decision Point>*** *of the protocol was recommended. The following issues are needed to be addressed among others:* **Technical/Scientific Issues** ***1. <Issue to be addressed>*** ***2. <Issue to be addressed>*** ***3. <Issue to be addressed>*** **Ethical Issues** ***1. <Issue to be addressed>*** ***2. <Issue to be addressed>*** ***3. <Issue to be addressed>*** ***<Total Number of Voters/Quorum> <Decision Point>*** *of the Informed Consent Form was recommended. The following issues are needed to be addressed among others:* ***1. <Issue to be addressed>*** ***2. <Issue to be addressed>*** ***3. <Issue to be addressed>***	

8. APPROVALS FROM THE PREVIOUS MONTH

8.1. Approved Protocols in Full Board

8.1.1.

IRB Protocol No	
Protocol Title	
Principal Investigator	
Sponsor	

Primary Reviewers	
Type of Review	
Turnaround Time	(_) days
Date of Initial Submission	(MMM/DD/YYYY)
Approval Date	(MMM/DD/YYYY)
Frequency of Continuing Review/Date of next review	Annually/ (MMM/DD/YYYY)

8.2. Approved Protocols in Expedited/SPARES

8.2.1.

IRB Protocol No	
Protocol Title	
Principal Investigator	
Sponsor	
Primary Reviewers	
Type of Review	
Turnaround Time	(_) days
Date of Initial Submission	(MMM/DD/YYYY)
Approval Date	(MMM/DD/YYYY)
Frequency of Continuing Review	Annually/ (MMM/DD/YYYY)

8.3. Approved Amendments

8.3.1. Approved Amendments

8.3.1.1.

IRB Protocol No	
Protocol Title	
Principal Investigator	
Sponsor/CRO	
Primary Reviewers	

Date of Submission of Amendment	(MMM/DD/YYYY)
Date of Approval of Amendment	(MMM/DD/YYYY)
Type of Review	
List of Amended Documents	

9. POST APPROVAL MONITORING

9.1. Protocol Amendments for Review and Approval

9.1.1.

IRB Protocol No	
Protocol Title	
Principal Investigator	
Sponsor/CRO	
Primary Reviewers	
Submission Date of Amendment	(MMM/DD/YYYY)
Type of Review	
List of Amendments	**Original Version** / **New Version** / **Reason**
Decision Points	☐ **Approval** ☐ **Major Modification** ☐ **Minor Modification** ☐ **Disapproval** ☐ **Pending Decision**
Reason for Decision	*<Total Number of Voters/Quorum> <Decision Point> of the amendment was recommended. The following issues are needed to be addressed among others:* ***1.*** *<Issue to be addressed>* ***2.*** *<Issue to be addressed>* ***3.*** *<Issue to be addressed>*
Members who reviewed the amendment	

9.2. Safety Reports

9.2.1.

IRB Protocol No		
Protocol Title		
Principal Investigator		
Sponsor/CRO		
Primary Reviewers		
SAE Subcommittee Members		
Initial Approval Date	(MMM/DD/YYYY)	
Submission Date of Report	(MMM/DD/YYYY)	
Type of Review		
SAE Report		
Decision Points	☐ **Request an amendment to the protocol or the consent form** ☐ **Request further information** ☐ **Suspend or terminate the study**	☐ **Take note and continue monitoring** ☐ **Others**
Reason for Decision	*<Total Number of Voters/Quorum> <Decision Point> of the safety report was recommended. The following issues are needed to be addressed among others:* ***1.*** *<Issue to be addressed>* ***2.*** *<Issue to be addressed>* ***3.*** *<Issue to be addressed>*	
Members who reviewed the safety report		

9.3. Protocol Deviations /Violation

9.3.1.

IRB Protocol No	
Protocol Title	

Principal Investigator		
Sponsor/CRO		
Primary Reviewers		
Initial Approval Date		
Submission Date of Protocol Deviation	(MMM/DD/YYYY)	
Type of Review		
Description of Deviation(s)/ Violation(s)		
Action(s) taken		
Decision Points	☐ **Amend Protocol** ☐ **Amend Informed Consent Form** ☐ **Suspend the study**	☐ **Terminate approval of current study** ☐ **For site Visit** ☐ **Continue Study and Monitor Compliance** ☐ **Request for further information**
Reason for Decision	*<Total Number of Voters/Quorum> <Decision Point> of the protocol deviation report was recommended. The following issues are needed to be addressed among others:* ***1.*** *<Issue to be addressed>* ***2.*** *<Issue to be addressed>* ***3.*** *<Issue to be addressed>*	

Members who reviewed the deviation/ violation	

9.4. Site Visit

9.4.1.

IRB Protocol No		
Protocol Title		
Principal Investigator		
Sponsor/CRO		
Primary Reviewers		
Initial Approval Date	(MMM/DD/YYYY)	
Date of Visit	(MMM/DD/YYYY)	
Name of IRB Representa-tives		
Duration of Visit (hours)		
Type of Review		
Decision Points	☐ **Continue study and post approval monitoring** ☐ **Amend protocol** ☐ **Amend Informed Consent** ☐ **Stop Recruitment**	☐ **Terminate Study** ☐ **Blacklist Principal Investigatot/Sponsor** ☐ **Recommend other corrective measures (specify)** ☐ **Others (spedify)**
Reason for Decision	*<Total Number of Voters/Quorum> <Decision Point> was recommended. The following issues are needed to be addressed among others:* ***1.*** *<Issue to be addressed>* ***2.*** *<Issue to be addressed>* ***3.*** *<Issue to be addressed>*	
Members who reviewed the site visit report		

9.5. Progress Report

9.5.1. Request for Renewal of Approval

9.5.1.1.

IRB Protocol No	
Protocol Title	
Principal Investigator	
Sponsor/CRO	
Primary Reviewers	
Date of last approval	(MMM/DD/YYYY)
Submission Date of Progress Report	(MMM/DD/YYYY)
Type of Review	
Reason of Renewal	
Annual Summary Report	

Number of subjects screened	
Number of subjects accrued	
Number of subjects completed	
Number of subjects who voluntarily withdrew consent after enrolling	
Number of subjects terminated/ withdrawn from the study by the investigator due to other reasons	
Summary of Amendments	***1.*** *<Brief Description of Amendment>* *<Document version>* *<Date of IRB Approval>* ***2.*** *<Brief Description of Amendment>* *<Document version>* *<Date of IRB Approval>*
Summary of SAEs/SUSARS	***For Onsite:*** *1. <AE reported>* *<Causality>* *<Date Reported to IRB>* ***For Offsite:*** *1. <AE reported >* *<Count>*

	Summary of Protocol Deviations/Violations	***1.*** *<Description of Protocol Deviation>* *<Corrective Action Taken>* *<Date Reported to IRB>* *<Type of Protocol Deviation>* ***2.*** *<Description of Protocol Deviation>* *<Corrective Action Taken>* *<Date Reported to IRB>* *<Type of Protocol Deviation>*
	Protocol Version No. and Date	
	Informed Consent Version No. and Date	
	Other pertinent documents (Please specify document) Version No. and Date	
Decision Points	☐ **Renew approval with no further action** **Date of renewal of approval: _____** ☐ **Approval pending:** —— **Recommend additional information** —— **Recommend modification**	☐ **Recommend suspension of:** —— **Enrollment of new subjects** —— **Research procedures in currently enrolled subjects** —— **The entire study** ☐ **Termination of approval** ☐ **Others**
Reason for Decision	*<Total Number of Voters/Quorum> <Decision Point> of the progress report was recommended. The following issues are needed to be addressed among others:* ***1.*** *<Issue to be addressed>* ***2.*** *<Issue to be addressed>* ***3.*** *<Issue to be addressed>*	
Members who reviewed the progress report		

9.5.2. Due for Renewal but No Progress Report Submitted

IRB Protocol No., Title and Principal Investigator	Date of Last Renewal	Date sent of Progress Report submission reminder	Board's Decision

9.6. Updates/Notifications

9.6.1.

IRB Protocol No		
Protocol Title		
Principal Investigator		
Sponsor/CRO		
Primary Reviewers		
Initial Approval Date	(MMM/DD/YYYY)	
Submission Date of Notification	(MMM/DD/YYYY)	
Type of Review		
Notification		
Decision Points	☐ **Acknowledged** ☐ **Request for information**	☐ **Recommend further action** ☐ **Others**
Reason for Decision	***<Total Number of Voters/Quorum> <Decision Point>*** *of the protocol deviation report was recommended. The following issues are needed to be addressed among others:* ***1.*** *<Issue to be addressed>* ***2.*** *<Issue to be addressed>* ***3.*** *<Issue to be addressed>*	
Members who reviewed the notification		

9.7. Final Report

9.7.1.

IRB Protocol No	
Protocol Title	
Principal Investigator	

Sponsor/CRO		
Primary Reviewers		
Initial Approval Date	(MMM/DD/YYYY)	
Submission Date of Final Report	(MMM/DD/YYYY)	
Type of Review		
Summary of Results		
Decision Points	☐ **Acknowledged** ☐ **Request for further information**	☐ **Recommend further action** ☐ **Others**
Reason for Decision	*<Total Number of Voters/Quorum> <Decision Point> of the final report was recommended. The following issues are needed to be addressed among others:* ***1.*** *<Issue to be addressed>* ***2.*** *<Issue to be addressed>* ***3.*** *<Issue to be addressed>*	
Members who reviewed the final report		

9.8. Early Study Termination

9.8.1.

IRB Protocol No	
Protocol Title	
Principal Investigator	
Sponsor/CRO	
Primary Reviewers	
Initial Approval Date	(MMM/DD/YYYY)
Submission Date of Termination Report	(MMM/DD/YYYY)

Type of Review		
Reason for Termination		
Decision Points	☐ **Acknowledged** ☐ **Request for information**	☐ **Recommend further action** ☐ **Others**
Reason for Decision	*<Total Number of Voters/Quorum of Full Board> <Decision Point> of the early study termination report was recommended. The following issues are needed to be addressed among others:* ***1.*** *<Issue to be addressed>* ***2.*** *<Issue to be addressed>* ***3.*** *<Issue to be addressed>*	
Members who reviewed the Early Study Termination Report		

9.9. Communications: Queries or Complaints

9.9.1.

IRB Protocol No	
Protocol Title	
Principal Investigator	
Sponsor/CRO	
Primary Reviewers	
Date received	(MMM/DD/YYYY)
Type of Review	
Queries/ Complaints	
Decision	
Members who reviewed the Query/ Complaint	

10. List of Exempted Protocols

IRB Code and Title	Principal Investigator	Date of Submission	Reason for Exemption

		(MMM/DD/YYYY)	

11. Financial Reports

11.1. Clinical Trial Agreement (CTA)

11.2. Financial Summary

Month	Expenses incurred for the month (Type of Expense and amount)	Review Fees received (amount)	Year-to-date financial balance
			(MMM/DD/YYYY)

12. Other Matters

11. Adjournment

12. Appendices

Prepared by:

<Signature above Printed Name of IRB Assistant>
<Designation>

Date (MMM/DD/YYYY)

Reviewed by:

<Signature above Printed Name of Member-Secretary>
<Designation>

Date (MMM/DD/YYYY)

Approved by:

<Signature above Printed Name of Chair>

Date (MMM/DD/YYYY)

<Designation>

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

CONFIDENTIALITY AGREEMENT FORM FOR NON-MEMBERS REQUESTING TO ACCESS MAKATI MEDICAL CENTER IRB DOCUMENTS (Form 4.3)

TO THE REQUESTOR: *ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, SIGN AND DATE THIS FORM.*

I, (Name Surname) as a non-member of the Makati Medical Center Institutional Review Board (MMC IRB), understand that the documents I am given access to by the IRB are confidential. I shall use the information only for the purpose indicated in this form and shall not duplicate in any form, give or distribute these documents to any person(s) without permission from the Makati Medical Center Institutional Review Board. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information private and confidential.

Requested document(s)

Reason for the Request

Number of copies requested		**Number of copies received**	

Name of the Recipient	**Signature**	**Date** (MMM/DD/YYYY)

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

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD
Document Tracker (Form 4.4A)

IRB Protocol No.:_____
Protocol Title:_____
_____
_____
Principal Investigator: _____
Department/Sponsor: _____
Contact Number/ Email Address.:_____

Document	Submitted by	Received by/Date	Member Secretary		Chair	Reviewers		Return to IRB	
			Sent by	Received by/Date	Date Signed	Sent by	Received by/Date	Returned by	Received by/Date

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD
Document Tracker (Form 4.4B)

IRB Protocol No.:_____
Protocol Title:_____
_____
_____
Principal Investigator: _____
Department/Sponsor: _____
Contact Number/ Email Address.:_____

INCOMING			OUTGOING		
Document	**Submitted by**	**Received by/Date**	**Document**	**Forwarded by**	**Received by/Date**

PROTOCOL INDEX
(Form 4.5)

Protocol Title		IRB Protocol Number	

Document Title	Date Submitted