MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

APPLICATION FORM FOR PROTOCOL REVIEW – INITIAL SUBMISSION (Form 2.1A)

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.

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

Preferred Contact	☐ Telephone ☐ Mobile ☐ Fax ☐ Email	**Department** (for Residents/Fellows)	Click here to enter text.

Conflict of Interest Declaration (Relationship with sponsor)	Are you a regular employee of the sponsor?	☐ Yes	☐ No
	Did you do consultancy or part time work for the sponsor?	☐ Yes	☐ No
	In the past year, did you receive Php250, 000 or more from the sponsor?	☐ Yes	☐ No
	Other ties with the sponsor	☐ Yes	☐ No
	Do you have any involvements in any other similar or competing trials? *(*For COVID-19 vaccine protocols only)*	☐ Yes	☐ No

Conflict of Interest Declaration *For non-sponsored protocols*	Click here to enter text.
Principal Investigator's Signature	Click here to enter text.
Protocol Title	Click here to enter text.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

Document Title	No. of Copies
☐ Protocol Summary Sheet (2.5)*	5
☐ Protocol Evaluation Form (2.7A, 2.7B)*	5
☐ Informed Consent Evaluation Form (Form 2.8)*	5
☐ Letter of Intent*	5
☐ **Endorsement Letter/Technical Approval (for in-house residents and fellows only)***	5
☐ **Protocol***	5
☐ Ethical Considerations and Statement of Agreement *	5
☐ **Informed Consent Form**	
English**	5
Filipino**	5
Local Dialect**	5
☐ **Assent Forms**	5
English**	
Filipino**	
☐ Case Report Forms (CRF) or Data*	5
☐ Collection Form*	5

Document Title	No. of Copies
☐ Recruitment Materials**	5
☐ Gantt Chart*	5
☐ Flow Chart*	5
☐ Study Budget*	5
☐ **FDA Approval****	5
☐ **Investigator's Brochure****	5
☐ Curriculum Vitae of Principal Investigator*	5
☐ GCP Certificate of Principal Investigator*	5
☐ Curriculum Vitae of Co-investigator/s*	5
☐ GCP Certificate of Co-investigator/s*	5
☐ CD and DVD Copy of the Protocol*	1
☐ Protocol Review Fee Receipt (for sponsored protocols)**	1

Legend:
* mandatory ** if applicable

Kindly submit the mentioned requirements to any of the following IRB Secretariat Staff located at the 7TH Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City:

1. John David S. Agustin (8888-999 Loc. 3972)
2. Kristine Mercado (8888-999 Loc. 7166)

CANCELLATION FEE
A cancellation fee of (Php15,000.00) will be charged to the sponsor or proponent if the protocol is not presented on date of review without any valid reason.

CLINICAL TRIAL AGREEMENT (CTA)
If applicable, a copy of the CTA may be submitted for parallel review by the Legal Counsel of Makati Medical Center.

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

APPLICATION FORM FOR PROTOCOL REVIEW – RESUBMISSION (Form 2.1B)

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.

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

Preferred Contact	☐ Telephone ☐ Mobile ☐ Fax ☐ Email	**Department** (for Residents/Fellows)	

Conflict of Interest Declaration (Relationship with sponsor)	Are you a regular employee of the sponsor?	☐ Yes	☐ No
	Did you do consultancy or part time work for the sponsor?	☐ Yes	☐ No
	In the past year, did you receive Php250, 000 or more from the sponsor?	☐ Yes	☐ No
	Other ties with the sponsor		

Conflict of Interest Declaration *For non-sponsored protocols*	Click here to enter text.
Principal Investigator's Signature	
Protocol Title	Click here to enter text.

Submitted documents in letter sized paper (please specify):

Click here to enter text.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

Kindly submit the mentioned requirements to any of the following IRB Secretariat Staff located at the 7TH Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City:

1. John David S. Agustin (8888-999 Loc. 3972)
2. Kristine D. Mercado (8888-999 Loc. 7166)

CANCELLATION FEE

A cancellation fee of (Php15, 000.00) will be charged to the sponsor or proponent if the protocol is not presented on date of review without any valid reason.

CLINICAL TRIAL AGREEMENT (CTA)

If applicable, a copy of the CTA may be submitted for parallel review by the Legal Counsel of Makati Medical Center.

Submitted by:

Click here to enter text.
Signature above Printed Name

Click here to enter text.
Date (MMM/DD/YYYY)

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

APPLICATION FORM FOR PROTOCOL REVIEW – AMENDMENT (Form 2.1C)

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.

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

Preferred Contact	☐ Telephone ☐ Mobile ☐ Fax ☐ Email	**Department** (for Residents/Fellows)	Click here to enter text.

Conflict of Interest Declaration (Relationship with sponsor)	Are you a regular employee of the sponsor?	☐ Yes	☐ No
	Did you do consultancy or part time work for the sponsor	☐ Yes	☐ No
	In the past year, did you receive Php250, 000 or more from the sponsor?	☐ Yes	☐ No
	Other ties with the sponsor		

Conflict of Interest Declaration *For non-sponsored protocols*	Click here to enter text.
Principal Investigator's Signature	Click here to enter text.
Protocol Title	Click here to enter text.
Date of Initial Approval (MMM/DD/YYYY)	Click here to enter text.

Submitted documents in letter sized paper (please specify):
Click here to enter text.

Kindly submit the mentioned requirements to any of the following IRB Secretariat Staff located at the 7TH Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City:

1. John David S. Agustin (8888-999 Loc. 3972)
2. Kristine D. Mercado (8888-999 Loc. 7166)

CANCELLATION FEE
A cancellation fee of (Php15, 000.00) will be charged to the sponsor or proponent if the protocol is not presented on date of review without any valid reason.

Submitted by:

Click here to enter text.
Signature above Printed Name

Click here to enter text.
Date (MMM/DD/YYYY)

REQUIREMENT CHECKLIST – INITIAL SUBMISSION (Form 2.2)

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**	
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		**Principal Investigator's Contact Number**	Click here to enter text.
Protocol Title	Click here to enter text.		

TO THE IRB SECRETARIAT: *CHECK FOR COMPLETENESS UPON SUBMISSION. INDICATE WITH (✓) MARK ON THE BOXES, IF APPLICAB*

Put a check mark (✓)	NUMBER OF COPIES	DOCUMENT SUBMITTED
	1	Accomplished forms: -Application Form (Form 2.1)
	5	-Protocol Summary Sheet (Form 2.5)
	5	-Protocol Evaluation Forms (Forms 2.7A and 2.7B)
	5	-Informed Consent Evaluation Form (Form 2.8)
	5	Letter of intent with itemized documents submitted.
	5	Accomplished Research Protocol Evaluation Forms (REFORM) signed by the Department Chair. (for In-house Residents, Fellows and Interns only)
	5	Detailed protocols and other protocol-related documents
	5	Gantt Chart of the Protocol
	5	Curriculum vitae and Good Clinical Practice Certificate (updated every 3 years) of the Principal Investigator and Co-investigator(s).
	1	CD or DVD copy of Protocol and other documents attached (in Microsoft Word) e.g. IRB Forms, Informed Consent, Case Report Form and Investigator's Brochure or Journal Reports, Literature Review for Trainees, if applicable.
	1	PowerPoint Presentation of the brief summary of the research burned in the CD
If applicable, submit the following:		
	5	Informed Consent Forms (English and Tagalog and/or other applicable dialect)
	5	Assent Form
	5	Case Report Forms or Data Collection Forms
	5	Diary Cards and other materials related to the study (e.g., recruitment materials, etc.)
	5	Study Budget
	5	Certification of FDA approval to conduct the trial in the Philippines (*parallel review by MMC IRB while awaiting FDA approval is allowed)
	5	Investigator's Brochure
	1	Protocol Review Fee (P60, 000.00) for sponsored study protocols conducted by consultants. (*Please make your check payable to Makati Medical Center – This fee is non-refundable and non-transferable once review is initiated.)

**Note: Handwritten forms will not be accepted.*

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

REQUIREMENT CHECKLIST – CTA
(Form 2.3)

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

Date of Submission (MMM/DD/YYYY)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol Number**	
Principal Investigator		**Co-investigator(s) (if any)**	
Principal Investigator's Contact Number		**Date of Approval** (MMM/DD/YYYY)	
Protocol Title			

CHECKLIST OF REQUIREMENT BEFORE SIGNING OF CLINICAL TRIAL AGREEMENT

TO THE IRB SECRETARIAT: *CHECK FOR COMPLETENESS UPON SUBMISSION. INDICATE WITH (✓) MARK ON THE TICK BOXES, IF APPLICABLE*

	DOCUMENT SUBMITTED
☐	If there will be a Clinical Trial Agreement between the sponsor and the institution, there will be an Institutional fee of (Php120,000.00). This will cover processing fees, legal review fee, etc. (*Please make your check payable to Makati Medical Center. Once the CTA is signed, this fee is non-refundable and non-transferable.)
☐	Letter of approval of protocol by MMC-IRB
☐	Endorsement letter by MMC-IRB Chair
☐	Six (6) original copies of the clinical trial agreement signed by the Sponsor and Principal Investigator **Note: 3 copies will be returned to the Principal Investigator. Please send a soft copy (preferably in Microsoft Word) to IRB.MMC2011@makatimed.net.ph*

Kindly submit the mentioned requirements to any of the following IRB Secretariat Staff located at the 7TH Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City:

1. John David S. Agustin (8888-999 Loc. 3972)
2. Kristine D. Mercado (8888-999 Loc. 7166)

Submitted by:

Click here to enter text.
Signature above Printed Name

Click here to enter text.
Date (MMM/DD/YYYY)

REQUIREMENT CHECKLIST – RESUBMISSION/ AMENDMENT PROTOCOL (Form 2.4)

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		**Principal Investigator's Contact Number**	Click here to enter text.
Date of Initial Approval (for amendment)	Click here to enter text.	**Type of Submission**	☒ Resubmission ☐ Amendment
Protocol Title	Click here to enter text.		
Submitted by	Click here to enter text.	**Signature**	

CHECKLIST OF REQUIREMENT BEFORE SIGNING OF CLINICAL TRIAL AGREEMENT

TO THE IRB SECRETARIAT: *CHECK FOR COMPLETENESS UPON SUBMISSION. INDICATE WITH (✓) CHECK MARK ON THE TICK BOXES, IF APPLICABLE.*

No. of Copies	DOCUMENT SUBMITTED
	Accomplished Forms
☐ 1	Application Form 2.1B (for resubmission) or Form 2.1C (for amendments)
☐ 4	Protocol Evaluation Form 2.7A
☐ 4	Protocol Evaluation Form for Resubmission 2.7C (for resubmission)
☐ 4	Protocol Amendment Review Form 3.2 (for amendments)
☐ 4	Letter of intent including the list of documents submitted
☐ 4	Letter from the adviser and chairman of the Research Committee of the Department attesting that the document resubmitted has been **reviewed and approved** (for In-house Interns, Residents and Fellows only)
☐ 4	Resubmitted or amended documents (including a copy of the IRB queries for resubmissions)

No. of Copies	DOCUMENT SUBMITTED
☐ 1	CD or DVD copy of Protocol and other documents attached e.g. Informed Consent, Case Report Form and Investigator's Brochure (saved in a Compact Disc)
	If changes were made on the protocol, informed consent forms, or other documents applicable:
☐	Highlight (or in bold and underlined) the changes made
☐	Place flagging on the page where the revisions are located

Kindly submit the mentioned requirements to the following IRB Secretariat Staff located at the 7TH Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City:

1. John David S. Agustin (8888-999 Loc. 3972)
2. Kristine D. Mercado (8888-999 Loc. 7166)

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

PROTOCOL SUMMARY SHEET
(Form 2.5)

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**	
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		**Principal Investigator's Contact Number**	Click here to enter text.
Protocol Title	Click here to enter text.		
Rationale	Click here to enter text.		
Objectives	Click here to enter text.		
Study Design/ Methodology	Click here to enter text.		
Inclusion of Criteria	Click here to enter text.		
Exclusion of Criteria	Click here to enter text.		
Data Analysis Plan	Click here to enter text.		
Study Outcomes (if applicable)	Click here to enter text.		

Kindly submit the mentioned requirements to the following IRB Secretariat Staff located at the 7TH Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City:

1. John David S. Agustin (8888-999 Loc. 3972)
2. Kristine Mercado (8888-999 Loc. 7166)

PROTOCOL INFORMATION
(Form 2.7A)

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**	
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**	
Department (for Residents/Fellows)	Click here to enter text.		
Protocol Title	Click here to enter text.		

Total Number of Participants	Click here to enter text.	**Number of Study Sites**	Click here to enter text.	**Duration of the Study**	Click here to enter text.

Type of Research	☐ Clinical Trial, phase:	☐ Epidemiological
	☐ Basic Science	☐ Social Science
	☐ Behavioral	☐ Others:
Study Design	☐ Prospective	☐ Retrospective

Description of the Study in brief (check (✓) all that applies)	Phase: _____		
	☐ Randomized	☐ Drug	☐ Use of Generic Materials
	☐ Double Blind	☐ Medical Device	☐ Multicenter Study
	☐ Single Blind	☐ Vaccine	☐ Global Protocol
	☐ Open Label	☐ Diagnostics	☐ Sponsor Initiated
	☐ Observational	☐ Questionnaire	☐ Investigator Initiated

For external protocols, has a MOA been signed between MMC the	☐ Yes	☐ Not Applicable
	☐ No	

external organization?	

Has this study protocol been reviewed by other IRBs?	☐ Yes **If yes, what was the IRB decision?* _____ ☐ No

Submitted by:

Click here to enter text.
Signature above Printed Name

Click here to enter text.
Date (MMM/DD/YYYY)

PROTOCOL EVALUATION FORM
FOR INITIAL REVIEW (Form 2.7B)

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.		

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 (✓) CHECK MARK ON THE SPACE PROVIDED.OTHERWISE, SPECIFY THE ISSUES ON THE SPACE PROVIDED. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

ASSESSMENT POINT	***LOCATION***	**REVIEWER'S COMMENTS**	
		APPROVED/ SUFFICIENT/ NO FURTHER COMMENT **(put a check ✓ mark)**	FOR REVISION (specify issues)
1. Title	Click here to enter text.		
2. Objectives	Click here to enter text.		
3. Literature Review/ Investigator's Brochure	Click here to enter text.		
4. Research Design	Click here to enter text.		
5. Sampling Design, Sample size or Number of subjects to be enrolled	Click here to enter text.		

6. Statistical/Data Analysis	Click here to enter text.		
7. Methodology	Click here to enter text.		
8. Control Arm (Placebo, if any)	Click here to enter text.		
9. Standard Therapy	Click here to enter text.		
10. Inclusion Criteria	Click here to enter text.		
11. Exclusion Criteria	Click here to enter text.		
12. Withdrawal or Discontinuation Criteria	Click here to enter text.		
13. Specimen Handling	Click here to enter text.		
14. Principal Investigator's Qualifications	Click here to enter text.		
15. Duration	Click here to enter text.		
16. Conflict of Interest a. Involvement of the Investigator in any other similar or competing trial *(*For COVID-19 vaccine*	Click here to enter text.		

protocols only)			
17. Privacy and Confidentiality	Click here to enter text.		

18. Informed Consent Process	Click here to enter text.		
19. Assent	Click here to enter text.		
20. Vulnerability	Click here to enter text.		
21. Recruitment	Click here to enter text.		
22. Risks a. Levels of Risk b. Types of Risk c. Source of Risk	Click here to enter text.		
23. Benefits a. Direct benefit to participants b. Benefits to society	Click here to enter text.		
24. Compensation	Click here to enter text.		
25. Community Consideration (i.e. recruiting, consenting the parent participants and their children	Click here to enter text.		
26. Participant's follow-up and management of the study	Click here to enter text.		
27. Provision for monitoring and auditing the conduct of the research, including constitution of the Data Safety Monitoring Board (DSMC)/ Food and Drug Administration	Click here to enter text.		

	(FDA) Approval			
28.	Data Collection Tool/ Case Report Form			

TO THE PRINCIPAL INVESTIGATOR: *PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Submitted by:

Click here to enter text.
Signature above Printed Name

Click here to enter text.
Date (MMM/DD/YYYY)

(To be filled out by IRB Primary Reviewer/Independent Consultant)

TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT: *PUT A (√) ON THE APPROPRIATE TICK BOX. IF THE PAPER IS FOR REVISION, SPECIFY MODIFICATION REQUIRED ON THE SPACE PROVIDED. IF THE PAPER IS DISAPPROVED, STIPULATE THE REASON FOR SUCH DECISION ON THE SPACE PROVIDED. PRINT NAME, SIGN AND DATE THIS FORM. PLEASE DO NOT USE PENCIL.*

NOTE: *FOR PROTOCOLS UNDER FULL BOARD REVIEW, THE PRIMARY REVIEWERS MUST BE PRESENT DURING THE DELIBERATION FOR FINAL DECISION. TO PREPARE FOR THE FULL BOARD MEETING, KINDLY RETURN THE ACCOMPLISHED EVALUATION FORMS (2.7B AND 2.8) TO THE IRB SECRETARIAT AT LEAST ONE (1) WEEK PRIOR TO THE SCHEDULED MEETING. THANK YOU.*

TO BE FILLED OUT BY THE PRIMARY REVIEWER

Reviewer's Recommendation

☐ Approval

☐ Minor Modification:
Summary of Revisions:

☐ Major Modification:
Summary of Revisions:

☐ Disapproval
Reason:

☐ Pending Decision
Reason:

Primary Reviewer's Name	Signature	Date (MMM/DD/YYYY)

TO THE IRB SECRETARIAT: *SPECIFY THE DELIBERATION DATE OF THE PROTOCOL*

Date of Meeting: _____
(MMM/DD/YYYY)

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

PROTOCOL EVALUATION FORM FOR RESUBMISSION (Form 2.7C)

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		**Principal Investigator's Contact Number**	Click here to enter text.
Protocol Title	Click here to enter text.		

INSTRUCTIONS

- **TO THE PRINCIPAL INVESTIGATOR:** *ON THE FIRST COLUMN, INDICATE THE IRB COMMENT AND RESPONSE AND/OR REVISIONS DONE. ON THE SECOND COLUMN, SPECIFY THE LOCATION/ PAGE NUMBER WHERE THE RESPONSE AND/ OR REVISIONS ARE PLACED. YOU MAY ADD MORE COLUMNS OR EXTRA PAGES, AS NEEDED.*
- **TO THE REVIEWER/ INDEPENDENT CONSULTANT:** *KINDLY STIPULATE ON THE THIRD COLUMN YOUR COMMENTS OR OTHER CLARIFICATIONS.*

IRB COMMENT AND RESPONSE AND/OR REVISION DONE	PAGE NUMBER OR LOCATION	REVIEWER'S COMMENTS
1. <MMC IRB Inquiry> <Principal Investigator's response>		
2. <MMC IRB Inquiry> <Principal Investigator's response>		
3. <MMC IRB Inquiry> <Principal Investigator's response>		
4. Others: <Revisions done>		

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT: *PUT A (√) CHECK MARK ON THE APPLICABLE TICK BOX. IF THE PAPER IS FOR REVISION, SPECIFY THE MODIFICATION REQUIRED ON THE SPACE PROVIDED. IF THE PAPER IS DISAPPROVED, STIPULATE THE REASON FOR SUCH DECISION ON THE SPACE PROVIDED. PRINT NAME, SIGN AND DATE ON THE SPACE PROVIDED.*

NOTE: *FOR PROTOCOLS UNDER FULL BOARD REVIEW, THE PRIMARY REVIEWERS MUST BE PRESENT DURING THE DELIBERATION FOR FINAL DECISION. TO PREPARE FOR THE FULL BOARD MEETING, KINDLY RETURN THE ACCOMPLISHED EVALUATION FORM (2.7C) TO THE IRB SECRETARIAT AT LEAST ONE (1) WEEK PRIOR TO THE SCHEDULED MEETING. THANK YOU.*

TO BE FILLED OUT BY THE PRIMARY REVIEWER

Reviewer's Recommendation

☐ Approval

☐ Minor Modification:

☐ Major Modification:

☐ Disapproval

Reason:

☐ Pending Decision

Reason:

Primary Reviewer's Name	**Signature**	**Date** (MMM/DD/YYYY)

TO THE IRB SECRETARIAT: *SPECIFY THE DELIBERATION DATE OF THE PROTOCOL.*

Date of Meeting: _____
(MMM/DD/YYYY)

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

PROTOCOL EVALUATION FORM FOR COMMUNITY RESEARCH (Form 2.7D)

TO THE PRINCIPAL INVESTGATOR: *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. THIS FORM IS USED TO COMMUNITY RESEARCH ONLY.*

Date of Submission (MMM/DD/YYYY)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol Number**	
Principal Investigator		**Co-investigator(s)** (if any)	
Principal Investigator's Signature		**Principal Investigator's Contact Number**	
Protocol Title			

FOR COMMUNITY RESEARCH

TO THE PRINCIPAL INVESTIGATOR: *INDICATE A (✓) MARK ON THE SPACE PROVIDED.*

Community Research Assessment

	Yes	No
Cultural considerations		
Approach prospective subjects for their individual consent only after obtaining permission from a community leader, a council of elders, or another designated authority.		
If there is cause for concern about the acceptability of the research in the community, there is a formal consultation with representatives designated by the community.		
There is substantial support in the community concerned. (See Guideline 8 Commentary, *Risks to groups of persons*.		
Is there an individual consent supplemented by community consultation?		
Benefits		
The expected benefits of the research to the community or to society at large, or contributions to scientific knowledge;		
The researcher gives no unjustifiable assurances about the benefits, risks or inconveniences of the research, for example, or induce a close relative or a community leader to influence a prospective subject's decision.		
Research in populations and communities with limited resources		
Is the research responsive to the health needs and the priorities of the population or community in which it is to be carried out?		
Will intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community?		
Ethical obligation of external sponsors to provide health-care services		
The research protocol should specify what health-care services will be made available, during and after the research, to the subjects themselves, to the community from which the subjects are drawn, or to the host country, and for how long.		
The details the arrangements is agreed by the sponsor, officials of the host country, other interested parties, and, when appropriate, the community from which subjects are to be drawn. The agreed arrangements are specified in the consent process and document.		
The source and amount of funding of the research: the organization that is sponsoring the research and a detailed account of the sponsor's financial commitments to the research institution, the investigators, the research subjects, and, when relevant, the community;		
Circumstances in which it might be considered inappropriate to publish findings, such as when the findings of an epidemiological, sociological or genetics study presents risks to the interests of a community or population or of a racially or ethnically defined group of people;		

Based on CIOMS guidelines

TO THE TECHNICAL REVIEWER (E.G., RESEARCH ADVISER OR RESEARCH COMMITTEE HEAD): *FOR INTERNS/ RESIDENTS/ FELLOWS, PRINT NAME, SIGN AND DATE THIS FORM ON THE SPACE PROVIDED.*
Technical Reviewer:

---------- ----------
Signature above Printed Name **Date** (MMM/DD/YYYY)

TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT: *PUT A (√) ON THE APPROPRIATE TICK BOX. IF THE PAPER IS FOR REVISION, SPECIFY MODIFICATION REQUIRED ON THE SPACE PROVIDED. IF THE PAPER IS DISAPPROVED, STIPULATE THE REASON FOR SUCH DECISION ON THE SPACE PROVIDED. PRINT NAME, SIGN AND DATE THIS FORM. PLEASE DO NOT USE PENCIL.*

NOTE: *FOR PROTOCOLS UNDER FULL BOARD REVIEW, THE PRIMARY REVIEWERS MUST BE PRESENT DURING THE DELIBERATION FOR FINAL DECISION. TO PREPARE FOR THE FULL BOARD MEETING, KINDLY RETURN THE ACCOMPLISHED EVALUATION FORMS (2.7B AND 2.8) TO THE IRB SECRETARIAT AT LEAST ONE (1) WEEK PRIOR TO THE SCHEDULED MEETING. THANK YOU.*

TO BE FILLED OUT BY THE PRIMARY REVIEWER

Reviewer's Recommendation

☐ Approval
☐ For Revision (*pls. specify*)
☐ Minor Modification:

☐ Major Modification:

☐ Disapproval
Reason:

Primary Reviewer's Name	Signature	Date (MMM/DD/YYYY)

TO THE IRB SECRETARIAT: *SPECIFY THE DELIBERATION DATE OF THE PROTOCOL.*

Date of Meeting: ----------
(MMM/DD/YYYY)

TO THE PRINCIPAL INVESTIGATOR: *PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Submitted by:

---------- ----------
Signature above Printed Name **Date** (MMM/DD/YYYY)

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

INFORMED CONSENT EVALUATION FORM
(Form 2.8)

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.	**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.		

TO BE FILLED OUT BY THE REVIEWER

TO THE REVIEWER/ INDEPENDENT CONSULTANT: *PUT A (✓) CHECK MARK ON THE TICK BOXES, IF APPLICABLE. SPECIFY YOUR COMMENTS ON THE SPACE PROVIDED.*

A. INFORMED CONSENT DOCUMENT REVIEW

1. Does the Informed Consent document state that the procedures are primarily intended for research?

   ☐ Yes ☐ No

   Comment:

2. Is there identification of those responsible and the procedure for obtaining the informed consent?

   ☐ Yes ☐ No

   Comment:

3. Does the Informed Consent document contain comprehensive and relevant information?

   ☐ Complete ☐ Incomplete

   Comment:

4. Is the information provided in the protocol consistent with those in the consent form?

   ☐ Consistent ☐ Inconsistent

   Comment:

5. Are study related risks mentioned in the consent form?

   ☐ Complete ☐ Incomplete

   Comment:

6. Is the language in the Informed Consent document

   Comment:

understandable?

☐ Clear ☐ Unclear

7. Is the Informed Consent translated into the local language/dialect?

☐ Clear ☐ Unclear

Comment:

8. Is there justification for inclusion of research individuals who cannot consent and the arrangement for obtaining consent from such consent?

☐ Yes ☐ No

Comment:

9. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants?

☐ Complete ☐ Incomplete

Comment:

10. Are names and contact numbers from the research team and the IRB in the informed consent?

☐ Yes ☐ No

Comment:

11. Is there protection of privacy and confidentiality of the research participants during and after the completion of the research?

☐ Yes ☐ No

Comment:

12. Is there any inducement in the participation?

☐ Likely ☐ Unlikely

Comment:

13. Is there provision for medical / psychosocial support?

☐ Appropriate ☐ Inappropriate

Comment:

14. Is there provision for treatment of study-related injuries?

☐ Appropriate ☐ Inappropriate

Comment:

15. Is there a set maximum acceptable amount for both monetary and non-monetary incentive or total compensation at Php 2,500 for each participant visit? *(*For COVID-19 vaccine protocols only)*

☐ Appropriate ☐ Inappropriate

Comment:

16. In case the total compensation is higher than Php 2,500, is there a reasonable justification to give higher compensation for research participants? *(*For COVID-19 vaccine protocols only)*

☐ Appropriate ☐ Inappropriate

Comment:

17. Is there a consent process in emergency situations in the research protocol?

☐ Appropriate ☐ Inappropriate

Comment:

18. Does the investigator ensure that the participants will receive available information during the course of the research relevant to their participation?

☐ Yes ☐ No

Comment:

19. Does the investigator ensure that the informed consent process is continuing?

☐ Yes ☐ No

Comment:

20. Does the Informed Consent contain provisions for receiving and responding to queries and complaints from participants or representatives during the course of the research?

☐ Yes ☐ No

Comment:

21. Is there a statement that participation is voluntary and that there are steps to be taken if research participants voluntarily withdraw during the course of the research?

☐ Yes ☐ No

Comment:

22. Are there provisions regarding indemnity and insurance?

☐ Yes ☐ No

Comment:

TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT: *PUT A (√) MARK ON THE TICK BOX NEXT TO YOUR RECOMMENDATION. IF THE PAPER IS FOR REVISION, SPECIFY THE MODIFICATION REQUIRED ON THE SPACE PROVIDED. IF THE PAPER IS DISAPPROVED, STIPULATE THE REASON FOR SUCH DECISION ON THE SPACE PROVIDED. PRINT NAME, SIGN AND DATE ON THE SPACE PROVIDED.*

NOTE: *FOR PROTOCOLS UNDER FULL BOARD REVIEW, THE PRIMARY REVIEWERS MUST BE PRESENT DURING THE DELIBERATION FOR FINAL DECISION. TO PREPARE FOR THE FULL BOARD MEETING, KINDLY RETURN THE ACCOMPLISHED EVALUATION FORMS (2.7B AND 2.8) TO THE IRB SECRETARIAT AT LEAST ONE (1) WEEK PRIOR TO THE SCHEDULED MEETING. THANK YOU.*

B. REVIEWER'S RECOMMENDATION

TO BE FILLED OUT BY THE PRIMARY REVIEWER

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.

Primary Reviewer's Name	Signature	Date (MMM/DD/YYYY)

TO THE IRB SECRETARIAT: *SPECIFY THE DELIBERATION DATE OF THE PROTOCOL.*

Date of Meeting: Click here to enter text.
(MMM/DD/YYYY)

TO THE PRINCIPAL INVESTIGATOR: *PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Submitted by:

Click here to enter text.
Signature above Printed Name

Click here to enter text.
Date (MMM/DD/YYYY)

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

NOTIFICATION OF IRB DECISION
(Form 2.9)

TO THE IRB SECRETARIAT: *ENCODE THE NECESSARY INFORMATION. SHADE THE APPROPRIATE 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)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol Number**	
Principal Investigator		**Co-investigator(s) (if any)**	
Protocol Title			
Protocol Version Number		**Version Date** (MMM/DD/YYYY)	
Other Documents			

Type of Submission	Type of Review
☐ Initial Submission ☐ Resubmission ☐ Amendment ☐ Others: _____	☐ Expedited (SPARES) ☐ Full board **Date of Meeting:** _____ (MMM/DD/YYYY)

The following are the issues or concerns raised by the three-man panel designated to review this protocol. Details of the action required from the investigator:
Technical/Scientific Review
Ethical Review
Informed Consent Assessment Points

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

Decision Points in the Protocol	☐ Approved ☐ Minor revisions required ☐ Major revisions required	☐ Disapproved ☐ Pending Decision until all issues are addressed
Decision Points in the Informed Consent Form	☐ Approved ☐ Minor revisions required ☐ Major revisions required	☐ Disapproved ☐ Pending Decision until all issues are addressed
Reason for decision	*12/12 _____ of the protocol was recommended. The following issues needed to be addressed, among others:* *12/12 _____ of the Informed Consent was recommended. Risk-benefit assessment was deemed acceptable. The following issues needed to be addressed, among others:*	
Deadline of Resubmission	***12 calendar days upon receipt of this notification.***	

PLEASE BE ADVISED THAT YOU MAY ONLY START THE CONDUCT OF THE STUDY AFTER APPROVAL

EXPECT THAT THE AVERAGE TURNAROUND TIME IN SIGNING THE NOTIFICATION IS 7 WORKING DAYS

REMINDERS:

1. ***YOU MAY ONLY START THE CONDUCT OF THE STUDY AFTER IT HAS BEEN APPROVED BY THE MMC-IRB.***
2. ***RESUBMISSION OF THE PROTOCOL MUST BE DONE WITHIN 12 DAYS (WHEN APPLICABLE).***
3. ***A FINAL REPORT IS MANDATORY AFTER THE COMPLETION OF THE RESEARCH. A FINAL REPORT IS REQUIRED FOR CLEARANCE PURPOSES FROM THE DIVISION OF MEDICAL EDUCATION AND RESEARCH.***

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

Kindly submit the re-submission requirements to any of the following IRB Secretariat Staff located at the 7TH Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City:

1. John David S. Agustin, RFP - 88888-999 loc. 3972
2. Kristine D. Mercado, RPM – 88888-999 loc. 7166

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

NOTIFICATION OF IRB DECISION - PROTOCOL DEVIATION (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)		**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)			
Protocol Deviation(s) Reported			
Reason for Termination			

Type of Review		
☐ Expedited	☐ Full board	**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:

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

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

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)		**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)			
Date of Submission of Final Protocol (MMM/DD/YYYY)			

Other Document(s) Filed:

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

IRB Decision
☐ Acknowledged ☐ Request for further information: ☐ Recommend further action _______________ ____ ☐ Others_______________ ____

Expect that the average turnaround time in signing the Notification of Final Report is 7 working days

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

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)		**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)			
Date of Submission of Progress Report (MMM/DD/YYYY)			

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

IRB Decision

☐ Uphold original 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):

Reason for Decision

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

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)		**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)			
Date of Submission of Site Visit (MMM/DD/YYYY)			
Date of IRB Meeting Site Visit was Reported (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)

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)		**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)			
Date of Serious Adverse Event Report (MMM/DD/YYYY)			
Term of the Adverse Event Report			
Date of IRB Meeting SAE was Reported (MMM/DD/YYYY)			
Reason for Termination			

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)		**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)			
Date of Submission of Early Study Termination (MMM/DD/YYYY)			
Reason for Early Study Termination			

IRB Decision

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

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

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)		**IRB Protocol Number**	
Name of the Participant			
Contact Information of the Participant			
Title of the Participating Study			
Participant's Request			
Action Taken and IRB Decision			

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

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)
	Date of Initial Review (MMM/DD/YYYY):	
Duration of Approval Period		
Frequency of Progress Report		
Date of Resubmission (MMM/DD/YYYY)		

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.

Expect that the average turnaround time in signing the Certificate of Approval is 7 working days.

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)

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

Date (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)			
Date of Submission of the Amendment(s) (MMM/DD/YYYY)			

List of Documents Approved:

Other Document(s) Filed:

Summary of Changes:

Amendment	Reason

Type of Review	☐ Full Board	☐ Expedited (SPARES)
	Date of Initial Review (MMM/DD/YYYY):	

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

Date of Approval	

Frequency of Progress Report	

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)

Post approval monitoring reports to be submitted by Principal Investigator to IRB

- Any amendments for IRB approval before implementing action.
- SAE and SUSAR reports (onsite: within 7 days, offsite: submitted along with the progress report)
- SAEs are submitted online via the link below:
  https://docs.google.com/forms/d/1NpL_xfOGuXItFyrWQcP-eX-zHkWkkGL_jPgxxRK0H_Y/viewform

- Progress report (submit according to frequency of continuing review and one (1) month before end of approval period.

- Final report after completion of protocol procedures at the study site
- Protocol deviation/violation (submit within two (2) weeks after incident/event)
- Comply with all relevant international and national guidelines and regulations
- Abide by the principles of good clinical practice and ethical research
- Comply with MMC's policy on Medication Management and Use: Management of Investigational Drugs.
- Refer to the attached form entitled, "Post-Approval Guidelines" for more details.

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

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

DEVICE ASSESSMENT FORM (FORM 2.11)
(SUPPLEMENTARY FORMS 2.1A & 2.7B, 2.8)

TO THE PRINCIPAL INVESTGATOR: *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)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol Number**	
Principal Investigator		**Co-investigator(s) (if any)**	
Principal Investigator's Contact Number		**Principal Signature**	
Protocol Title			

GENERAL INFORMATION OF STUDY DEVICE	
Name of Study Device	
Sponsor/ Manufacturer	
Indication for Use	

TO THE PRINCIPAL INVESTIGATOR: *ON THE SECOND COLUMN, SPECIFY THE LOCATION/ PAGE NUMBER OF THE ASSESSMENT POINT. INDICATE* ***N/A*** *IF NOT APPLICABLE*

TO THE REVIEWER/ INDEPENDENT CONSULTANT: *KINDLY STIPULATE ON THE THIRD COLUMN YOUR COMMENTS OR OTHER CLARIFICATIONS. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

PROTOCOL EVALUATION ON STUDY DEVICE		
ASSSESSMENT POINT	**LOCATION**	**REVIEWER'S COMMENT**
1. Description of the device/ Product information including handling and storage requirements.		
2. Proposed investigational plan (Use of the device in the study)		
3. Reports of prior investigations conducted with the device		
4. FDA Approval, IDE Number		
5. Risk assessment determination for new investigational device (Significant Risk or Non Significant Risk) and its rationale		
6. Choice of comparator and justification (if applicable)		
7. Summary of the necessary training and the experience needed to use the investigational device		
8. Device control, access and accountability		
9. List of additional procedures (example: surgery), medical device or medication to be used as part of the investigational study		
10. Risk-benefit assessment		
11. Safety and effectiveness/ performance assessments		
12. Prohibition against promotion or commercialization of, and certain other practices relative to, investigational devices		
13. References		

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

TO THE PRINCIPAL INVESTIGATOR: *ON THE SECOND COLUMN, PUT A (✓) MARK ON THE APPROPRIATE TICK BOX. INDICATE* ***N/A*** *IF NOT APPLICABLE*

TO THE REVIEWER/ INDEPENDENT CONSULTANT: *KINDLY STIPULATE ON THE THIRD COLUMN YOUR COMMENTS OR OTHER CLARIFICATIONS. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

ASSESSMENT OF STUDY DEVICE			
RISK INVOLVED	To be filled out by the Principal Investigator		**REVIEWER'S COMMENTS**
Significant Risk Study Device **A Study Device that meets the definition below is considered as Significant Risk Study Device.*	**Yes**	**No**	
Intended as an implant and presents a potential serious risk to the health, safety or welfare of a subject.			
Is represented to be for use supporting or sustaining human life and presents a potential serious risk to the health, safety or welfare of a subject.			
Is for use of a substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety or welfare of a subject.			
Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject;			
Non Significant Risk Device **A study device that does not meet the definition of Significant Risk device study is considered as Non significant Risk device Study.*			
IDE Exempt Study Device			

Submitted by:

Signature above Printed Name

Date (MMM/DD/YYYY)

TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT: *PUT A (✓) MARK ON THE APPROPRIATE TICK BOX. IF THE PAPER IS FOR REVISION, SPECIFY MODIFICATION REQUIRED ON THE SPACE PROVIDED. IF THE PAPER IS DISAPPROVED, STIPULATE THE REASON FOR SUCH DECISION ON THE SPACE PROVIDED. PRINT NAME, SIGN AND DATE THIS FORM. PLEASE DO NOT USE PENCIL.*

NOTE: *FOR PROTOCOLS UNDER FULL BOARD REVIEW, THE PRIMARY REVIEWERS MUST BE PRESENT DURING THE DELIBERATION FOR FINAL DECISION. TO PREPARE FOR THE FULL BOARD MEETING, KINDLY RETURN THE ACCOMPLISHED EVALUATION FORMS (2.7B, 2.8, AND 2.11) TO THE IRB SECRETARIAT AT LEAST ONE (1) WEEK PRIOR TO THE SCHEDULED MEETING. THANK YOU.*

TO BE FILLED OUT BY THE PRIMARY REVIEWER

Reviewer's Recommendation

☐ Approval
☐ For Revision (*pls. specify*)
☐ Minor Modification:

☐ Major Modification:

☐ Disapproval
Reason:

Primary Reviewer's Name	Signature	Date (MMM/DD/YYYY)