Chapter II : Initial Protocol Review and Approval	Document Code: **IRB-SOP-1120-IPR-002-08**	
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***REVIEW: This Standard Operating Procedure is reviewed every 3 years or earlier as indicated.**

2.1 Protocol Submission

2.1.1 Purpose

To describe the initial review procedures of the Makati Medical Center Institutional Review Board (MMC IRB) from the time that the MMC IRB receives the protocol and related documents until the acknowledgement receipt is provided to the Principal Investigator (PI).

2.1.2 Scope

The MMC IRB accepts the protocols for review for researches done in Makati Medical Center (MMC) and protocols done by Makati Medical Center active and associate active staff, house staff in areas outside the hospital premises.

2.1.3 Responsibility

The MMC IRB Secretariat manages all protocol submissions to the MMC IRB. It covers the actions to be done from the time of submission to the filing of the original protocol package in the Active Study File cabinet.

2.1.4 Process Flow/Steps

NO	ACTIVITY	RESPONSIBILIT	TIMELINE
1	Receive the initial protocol package for review and check the completeness of the document requirements **(Form 2.2)** together with the IRB Application Form (**Form 2.1A)** signed by the Principal Investigator and the Protocol Summary sheet **(Form 2.5)**. *For investigator-initiated protocols, the research committee of each Department ensures that the Technical Reviewer has signed the Protocol Evaluation Form (**Form 2.7B**) and an endorsement by the department/ unit is provided.	Secretariat	1 working day
2	Assign a permanent code to the protocol and encode in database.	Secretariat	1 working day

3	Acknowledge receipt of the complete documents is provided by giving a duplicate copy of the application form(**Form 2.1A)** to the person submitting the package. Attach the original copy to the protocol package to be kept in the IRB. This will commense the turn around time of rview and approval which is 4 weeks from the stime of submission to the notice of decision	Secretariat	1 working day
4	File the original package in a properly coded Protocol File folder and place it in the Active Study File cabinet.	Secretariat	1 working day

Detailed instructions

2.1.4.1 Only complete submissions are accepted on the 3rd week of the month. All protocols, which are determined to undergo a review (expedited through SPARES or full board), are scheduled for review and deliberation on the next scheduled meeting. Turnaround time from protocol submission to communication of MMC IRB decision is 4 weeks. Submitted protocols need technical approval and ethical review.

A. For Makati Medical Center protocols, the Department Research Review Committee should have addressed the technical issues apparent to the study protocol. The IRB Secretariat will provide the Board-approved criteria for the guidance of the different Departments in their review of the protocols. The research committee head or research adviser endorses the protocols to MMC IRB for ethical review and approval by accomplishing the Research Proposal Evaluation Form (REFORM).

B. For non-Makati Medical Center protocols, the research protocol undergoes technical and ethical review by the IRB.

Upon submission of the initial protocol for Makati Medical Center IRB review, the principal investigator or his/her representative should ensure that the protocol follows the standard protocol format and contains a Protocol Summary Sheet **(Form 2.5)**

Secretariat checks the completeness of the documents being submitted based on the IRB checklist **(Form 2.2).**

A protocol package includes the following:

A. One copy of all the documents in the checklist are submitted to the IRB Office for review
B. Letter of intent with itemized documents submitted. This document identifies the items submitted and specifies the purpose of submission. The letter is addressed to the chair of the MMC IRB.
C. Curriculum vitae and Good Clinical Practice Certificate (updated every 3 years) of the principal investigator and other co-investigators of the study to present the qualifications of the principal investigator and co-investigators
D. Certification of Food and Drug Administration (FDA) approval to conduct the trial in the Philippines. This is only applicable to studies involving products that may be intended to be marketed in the Philippines. According to the FDA Circular No. 2012-007, "all clinical trials, from Phase I to IV, including amendment(s) thereto, require mandatory approval from the FDA." A parallel review may be done by MMC-IRB while awaiting FDA approval is allowed.
E. Detailed protocol. This is a document that describes the background, objectives, inclusion and exclusion criteria, study design, methodology, and sample size of the study to be reviewed.
F. Informed consent forms (applicable for prospective studies) in English, Tagalog and other dialect if applicable (See attached Guidelines on Submitting an Informed Consent Form). These are the forms utilized in obtaining permission from the individual to participate in the study.
G. Assent Forms (if applicable). These are the forms used to attain authorization of a study participant incapable of providing an informed consent.
H. Case Report Forms or Data Collection Forms. These are printed or electronic documents used to gather all the information necessary for the study.
I. Diary Cards and other materials related to the study (e.g. recruitment materials, etc.).
J. Study Budget is the total amount of money for a study.
K. Accomplished Application Form **(Form 2.1A),** Protocol Summary Form **(Form 2.5)**, Protocol Evaluation **(Form 2.7A and 2.7B)**, Gantt Chart (to indicate the timeline of the study) and Flow Chart of the Protocol (to illustrate the methodology of the study). These are for both the sponsored and investigator-initiated protocols.

L. Investigator's Brochure (for drug trials)/ printed references (for investigator-initiated protocols).

M. Protocol and other documents attached as enumerated in the Protocol package e.g. Powerpoint presentation of the summary of the research, Informed Consent, Case Report Form and Investigator's Brochure or Journal Reports, Literature Review for Trainees if applicable, are submitted to the IRB official email on the 3rd week of the month.

N. Protocol Review Fee

The protocol review fee is Php 60,000.00 (net of withholding tax) for sponsor-initiated protocols and Php 30,000.00 (net of withholding tax) for investigator-initiated protocols, payable to "Makati Medical Center". An official Statement of Account for the review fee may be requested from the Secretariat Staff to process the payment.

For cash/check payments, the Investigator/Member of the Study Team should directly pay to the MMC Cashier 3 located on the Ground Floor of the MMC Tower 1 and ask the cashier to credit payment to IRB Cost Code 6508000. The Official Receipt must reflect "IRB Review fee" under particulars, and a copy of the receipt is submitted to the IRB Secretariat as one of the requirements for initial submission.

For payments made via wire transfer, the Investigator/Member of the Study team should forward the wire transfer details to the IRB Secretariat via email as one of the requirements for initial submission. The IRB Secretariat will then facilitate confirmation of payment from Finance. Once confirmed, a printed copy of the wire transfer payment and confirmation from Finance must be submitted to the MMC Cashier 3 located on the Ground Floor of the MMC Tower 1, for issuance of Official Receipt and ask the cashier to credit payment to IRB Cost Code 6508000. The Official Receipt must reflect "IRB Review fee" under particulars, and the IRB Secretariat gives a copy of the receipt to the Investigator/Member of the Study Team.

The review fee is non-refundable and non-transferable once review is initiated. Should there be an intent by the company to publish a trainee-initiated protocol, all applicable fee is applied (e.g., IRB review fee).

2.1.4.2 Assign a code to the package. The code will be communicated to the principal investigator in subsequent communications regarding the protocol. The assigned code in encoded in the protocol database

2.1.4.3 Ensure that the Principal Investigator has signed the Makati Medical Center IRB Application Form for Protocol Review **(Form 2.1A).** Secretariat makes a copy of the filled-out application form, keep the original copy for the IRB files and gives the duplicate to the principal investigator (PI) or his/her representative. This serves as the acknowledgement receipt. This will commense the turn around time of review and approval which is 4 weeks from the time of submission to the notice of decision

2.1.4.4 Secretariat files the protocol.

A. Put the original copies in a protocol file folder
B. Put the code of the protocol on the side of the file folder
C. File the folder in the Active Study Files cabinet
D. Prepare the protocol index and document tracker

2.2 Protocol Screening

2.2.1 Purpose

To describe the process of determining the type of review a protocol undergoes and to assign the primary reviewers.

2.2.2 Scope

This applies to all submission to the MMC IRB for review and approval.

2.2.3 Responsibility

The Secretariat Staff manages the screening process. The Member-Secretary recommends the type of review for the protocol submitted according to the criteria. This is also the process when the primary reviewers and independent consultants are assigned to review the research proposal. The Chair approves the recommendation of the Member-Secretary.

2.2.4 Process Flow

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Recommendation of type of review using the Type of Review Form **(Form 2.6)**	Member-Secretary	1 working day
2	Identification of primary reviewers and independent consultant (if necessary) assigned to review the research proposal.	Member-Secretary	1 working day
3	Approval of the type of review **(Form 2.6)** and assigned primary reviewers and independent consultant.	Chair	1 working day
4	Type of Review form **(Form 2.6)** is kept in the protocol file. Database is updated accordingly.	Secretariat	1 working day
5	Distribution of protocol package to assigned reviewers	Secretariat	1 working day

Detailed Instructions

2.2.4.1 Upon submission of the protocol and the requirements, the secretariat provides the Member-Secretary with the Type of Review Form (**Form 2.6)**.

Member-Secretary recommends the type of review according the criteria

EX	EXEMPTION CRITERIA
1	Study that does not involve human participants nor identifiable tissue, biological samples and data
2	Study design is meta-analysis and/or systematic with non-identifiable data
3	Case Report
4	Study with less than minimal risk or harm
5	Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests

Protocols are exempted from review if there are less than minimal risks. For protocols which are exempted from IRB review, the principal investigator is required to submit a copy of the protocol and a cover letter to justify the request for exemption of review.

The Member secretary recommends and the IRB Chair decides if the research requires IRB review and approval.

A Letter of Exemption is provided to the principal investigator regarding the decision of exemption. The principal investigator of researches exempted from IRB review submits a copy of the final paper to the IRB for the completion of the research.

ISER	EXPEDITED REVIEW (SPARES)
1	Protocols of a non-confidential nature (not of a private character, e.g. relate to sexual preference etc., or not about a sensitive issue that may cause social stigma), not likely to harm the status or interests of the study participants and not likely to offend the sensibilities nor cause psychological stress of the people involved.
2	Protocols <u>not</u> involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to participate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent).
3	Protocols that involve collection of anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).
4	Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis

ISFB	FULL BOARD REVIEW
1	Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3)
2	Phase 4 intervention research involving drugs, biologics or device
3	Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc., or about sensitive issues that may cause social stigma) that may cause psychological, legal, economic and other social harm
4	Protocols involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to participate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent) that require additional protection from the IRB during review
5	Protocols that involve collection of identifiable biological specimens for research

2.2.4.1 For protocol requiring review (expedited/SPARES or full board), Member-Secretary recommends the assigned primary reviewers, selected based on the expertise related to the protocol.

A. Primary reviewers are selected on the basis of expertise related to the protocol. Research proposals are given to all members; both medical and non-medical or lay members, institutional and non-institutional members for review. The medical/ scientific members analyze the scientific and ethical procedures in the protocol while the lay/ non-institutional members focus their assessment on the informed consent form. The Informed Consent Form can be reviewed by both the lay and paramedical/ nurse/ pharmacist member. Review assignments should take into consideration the appropriate mix of old and new members.

B. Member-Secretariat using **Form 2.6**, nominates two or more MMC IRB members (Medical member with related expertise to review the protocol and a non-medical person to review the informed consent).The assignments are equitably distributed taking in consideration the expertise of the reviewers.

C. An independent consultant may be invited to provide expert opinion about a protocol.

2.2.4.2 Chair approves the recommended assigned primary reviewers **(Form 2.6)** by the Member secretary and signs the Type of Review form

2.2.4.3 Secretariat enters in the IRB database the names of the primary reviewers.

Type of Review Form **(Form 2.6)** is kept in the protocol file.

2.1.5.5 Secretariat prepares the protocol for distribution to the reviewers. Include copies of the "Protocol Evaluation Forms" **(Form 2.7A and 2.7B)** and the "Informed Consent Evaluation Form" **(Form 2.8)** in the package.

Prepare a transmittal letter with the name of the reviewer.

Note in the protocol tracker the date of actual delivery of the protocol package and the expected return. The protocol tracker is to be signed by the reviewer or a representative upon receipt,

Secretariat sends the protocol and related documents to the selected primary reviewers.

2.3 Protocol Evaluation

2.3.1 Purpose

To describe the procedures of protocol evaluation to review the scientific/ technical and ethical aspects of the protocol.

2.3.2 Scope

The Study Evaluation Forms **(Form 2.7A, 2.7B and 2.7C)** are designed to standardize the review process and to facilitate reporting of recommendation and comments given to each individual protocol and related documents.

There are two (2) Makati Medical Center IRB Evaluation Forms for protocol review:

A. Protocol Evaluation Forms **(Form 2.7A, 2.7B and 2.7C)**
B. Informed Consent Evaluation Form **(Form 2.8)**

This SOP applies to the use of the Study Assessment Forms in the review and assessment of protocols and related documents submitted to Makati Medical Center IRB for initial review and approval by the IRB.

2.3.3 Responsibility

It is the responsibility of the Makati Medical Center IRB reviewers to individually fill-out the evaluation forms **(Form 2.7A, 2.7B and 2.7C)** after reviewing each study protocol. Any comment, evaluation, recommendation and the initial decision of each reviewer regarding a protocol are all noted in these two forms. The Secretariat is responsible for recording and filing the Makati Medical Center IRB's action, relevant points and deliberation about a particular protocol, including the comments for specific action. The decision regarding each reviewed protocol will be reflected in the Minutes of the meeting.

2.3.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Evaluate the scientific/ technical and ethical aspect of the protocol ⬇	Primary Reviewers	3 working days
2	Fill out the Protocol Evaluation Forms **(Form 2.7A, 2.7B, 2.7C and 2.8)** during review of the study protocol and related documents. ⬇	Primary Reviewers	
3	Submit accomplished Study Evaluation Forms **(Form 2.7A, 2.7B, 2.7C and 2.8)** to the Secretariat ⬇	Primary Reviewers	
4	Check forms for completeness and file in the protocol folder. Update the Protocol index and tracker ⬇	Secretariat	1 working day
5	Include the protocol review in the agenda of the meeting for the month (spares or full board review) ⬇	Secretariat	1 working day
6	Review the protocol either during the full board or SPARES review meeting and decide ⬇	Primary Reviewers/ Members	1 working day
7	Communicate the decision of the reviewers/ board to the principal investigator **(Form 2.9)** ⬇	Secretariat	1 working day
8	Prepare an Approval letter **(Form 2.10)** ⬇	Secretariat	1 working day
9	File copies of duly accomplished forms in the Study File Folder of the particular protocol	Secretariat	1 working day

10	⬇ File index of document and protocol tracker **(Form 4.4A and 4.4B)** on each protocol folder for protocol tracking and to ensure completeness of documents.	Secretariat	1 working day

Detailed instruction

2.3.4.1 Protocol Review

The primary reviewers:

A. Use the Protocol Evaluation Form (**Form 2.7A, 2.7B and 2.7C)** for the protocol and the Informed Consent Evaluation Form (**Form 2.8**) to review the protocol and the consent form and write relevant comments.
   - Check Protocol Evaluation Form (Form 2.7B) for Technical Review by the Department/ Unit of Trainee.

B. Check the CV or information about the investigators (including GCP training for clinical trials), the study sites and other protocol related documents, including advertisements.
   1) Consider whether study and training background of the principal investigator/s are related to the study.
   2) Look for disclosure or declaration of potential conflicts of interest.
   3) Non-physician principal investigators should be advised by a physician when necessary.
   4) Determine if the facilities and infrastructure at study sites can accommodate the study.

C. Check the "Assent Form" if the protocol involves children or other vulnerable groups as study participants based on PHREB guidelines. The procedure for getting the assent of vulnerable participants should be clear (the objective of the study and the procedures to be done should be explained to the child or vulnerable participant separately).

D. Note the following technical and ethical Review Guidelines:
   1) Protocol manifests scientific validity and contains all the standard sections to ensure scientific soundness.
   2) In assessing the degree of risk against the benefit, determine whether the risks are reasonable in relation to anticipated benefits; and/or if the risks can be minimized.

3) Study participants are selected equitably especially if randomization is not to be used. Study participant's information sheet should be clear, complete and written in understandable language.
4) There is voluntary, non-coercive recruitment of study participants.
5) Informed Consent is adequate, easy to understand and properly documented.
6) There should be a translation of the Informed Consent document into the local dialect, which should be comprehensible by the general public.
7) Procedure for getting the Informed Consent is clear and unbiased.
8) Persons who are responsible for getting the Informed Consent are named and they introduce themselves to the study participants.
9) Research plan makes adequate provision for monitoring data collection to ensure the safety of study participants, where appropriate.
10) There are adequate provisions to protect the privacy of study participants and to maintain the confidentiality of data, where appropriate.
11) There is provision for compensation to study participants. There should be reasonable provision for medical/psychosocial support; treatment for study related injuries, as well as compensation for participation to cover expenses like transport and lost wages because of participation.
12) There are appropriate safeguards included to protect vulnerable study participants.
13) Contact persons or Investigators with address and phone numbers are included in the Informed Consent.
14) There is clear justification for the use of biological materials and a separate consent form for future use of biological specimens.
15) There are appropriate contracts or memoranda of understanding especially in collaborative studies.

E. For community studies, examine community involvement and impact/benefit of the study to the community and/or the institution. If relevant, the reviewer looks for the following in the protocol:
1) Involvement of local researchers and institutions in the protocol design, analysis and publication of the results
2) Contribution to development of local capacity for research and treatment in benefit to local communities
3) Sharing of study results with the participants/ community
4) Cultural Considerations
   a. Approach prospective subjects for their individual consent only after obtaining permission from a community leader, a council of elders, or another designated authority.
   b. Community Consultation: 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.

c. There is substantial support in the community concerned. (See Guideline 8 Commentary, *Risks to groups of persons*.

d. There is an individual consent supplemented by community consultation.

5) Benefits

a. There are expected benefits of the research to the community or to society at large, or contributions to scientific knowledge.

b. The researcher gives no unjustifiable assurances about the benefits, risks or inconveniences of the research, for example, or induces a close relative or a community leader to influence a prospective subject's decision.

6) Research in populations and communities with limited resources

a. The research is responsive to the health needs and the priorities of the population or community in which it is to be carried out.

b. The intervention or product developed, or knowledge generated will be made reasonably available for the benefit of that population or community.

7) Ethical obligation of external sponsors to provide health-care services

a. The research protocol specifies 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.

b. 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.

c. The source and amount of funding of the research are specified: 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.

d. Circumstances in which it might be 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 are considered.

2.3.4.2 MMC IRB primary reviewers individually fill out the following forms for each protocol.

Protocol Evaluation Form (**Form 2.7A, 2.7B and 2.7C)** ensures assessment of the following:

Technical/scientific and ethical aspects of the protocol as follows:

A. Title
B. Objectives of the study
C. Review of literature
D. Research Design
E. Sampling Design/Sample size
F. Statistical/Data Analysis Plan
G. Methodology and data management
H. Control arms (placebo, if any)
I. Standard Therapy
J. Inclusion criteria
K. Exclusion criteria
L. Withdrawal or discontinuation criteria
M. Duration
N. Principal Investigator's Qualification
O. Specimen Handling
P. Recruitment
Q. Conflict of interest
R. Privacy and confidentiality:
S. Informed consent process:
T. Assent:
U. Vulnerability:
V. Risks (Level Risk, Types of Risk, Source of Risk):
W. Benefits (Direct Benefit to Participants, Benefits to Society/Social Value):
X. Compensation:
Y. Community consideration:
Z. Participant's follow-up and management of the study:
AA. Provision for monitoring and auditing the conduct of the research, including constitution of data safety monitoring board (DSMC)
BB. Data Collection Tool/Case Report Form

Informed Consent Evaluation Form (**Form 2.8)** checks if the following are complied with:

A. Full disclosure of information, including risks

B. Benefits that may be derived from the study
C. Use of understandable language
D. Voluntary participation
E. Confidentiality
F. Appropriate person is to sign the consent form
G. Indemnity and Insurance

2.3.4.3 Primary reviewer signs and submits the evaluation forms together with the reviewed protocol to the Secretariat.

- When the primary reviewers fail to review and give their assessment for the protocol submission (either Expedited/SPARES or Full Board Review) within three (3) working days, the submission will be forwarded to the Chair to ensure that review decision and responses will be provided in a timely manner.

2.3.4.4 Secretariat checks whether the forms are complete, compiles the checklists and submits these to the Member-Secretary and/or Chair.

- Member-Secretary and/or Chair reviews the compiled checklists.

2.3.4.5 The Secretariat includes the protocol in the agenda of the next Makati Medical Center IRB full board or SPARES meeting for discussion and decision (Please refer to Section 1.1.9.4 of MMC IRB SOP Chapter 1).

2.3.4.6 The Primary Reviewers/ Members review the protocol either during the full board meeting or SPARES review.

2.3.4.7 If there are revisions required, these are communicated to the Principal Investigator who has to resubmit the revised protocol and related documents before review and approval is given **(Form 2.9).** Resubmissions are accepted every second Wednesday of the month.

In expedited/ SPARES review, the secretariat communicates the revisions required (if any) to the Principal Investigator who has to resubmit the revised protocol and related documents before approval is given. Approved expedited/ SPARES protocols are reported during the full board meeting for documentation.

The time stamp stops after the result of review and decision is provided awaiting resubmission is necessary. Turn around time continues after resubmission is provided.

If resubmission is not given within 6 months, then the protocol is considered inactive and will be archived. Update database accordingly.

2.3.4.8 An approval letter is prepared, signed by the Chair and sent to the Principal Investigator once a protocol is approved **(Form 2.10)**.

For protocols that have Informed Consent Forms. An IRB Stamp of Approval is required before distribution of Informed Consent Forms to patients/participants.

***NB When the primary reviewers fail to review and give their assessment for the protocol submission (either Expedited/SPARES or Full Board Review) within three (3) working days, the submission will be forwarded to the Chair to ensure that review decision and responses will be provided in a timely manner.*

2.3.4.9 A copy of the signed letter is retained in the protocol file folder.

2.3.4.10 The Secretariat updates the protocol database, tracker **(Form 4.4A and Form 4.4.B)** and index**.**

2.4 Full Board Review

2.4.1 Purpose

To describe the procedures when protocol submissions are classified for full board review.

2.4.2 Scope

This SOP applies to the review and approval of study protocols or amendments with medium to high risk to study participants and major revisions in the protocol or informed consent. The submission procedures are the same as first time submission.

2.4.3 Responsibility

It is the responsibility of the Secretariat to manage the document submission, send protocol documents to the primary reviewers, refer the protocol to full board meeting for discussion and decision, communicate the review results to the Principal Investigator, keep copies of the documents in the protocol files and update the protocol entry in the IRB database.

The Secretariat is responsible for receiving, verifying and managing the contents of both the hard copies and the electronic version (if any) of the submitted protocol package. In addition, the Secretariat should create a specific protocol file, make copies of the file and then distribute the copies to the Makati Medical Center IRB reviewers, together with a cover letter where the due date for returning the reviewed protocol is indicated as well as the schedule of meeting when the protocol will be discussed.

It is the responsibility of the assigned reviewers to thoroughly review the study protocols, give their decision, observation and comments and put all of this in the Study Assessment Forms **(Form 2.7A, 2.7B and 2.8)** before returning the reviewed protocol and assessment form to the Secretariat on the due date. Reviewers are present during the meeting for final deliberation and discussion.

2.4.4 Process Flow/Steps

NO	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive the complete submitted documents (with **Form 2.2, or 2.4**) and forwards to Member-Secretary and Chair	Secretariat	1 working day
2	Determine that the protocol qualifies for Full Board review **(Form 2.6)** and assign reviewers	Member-Secretary Chair	1 working day 1 working day
3	Review the protocol documents, accomplish the assessment forms **(Form 2.7A, 2.7B and 2.8)** and submit the decision/ recommendation to the Secretariat	Primary Reviewers	3 working days
4	Include the protocol in the meeting agenda **(Form 4.1)** for discussion to arrive at a decision through full board	Secretariat/ Members	1 working day
5	Communicate board decision to the principal investigator **(Form 2.9)**	Secretariat/ Chair	1 working day
6	If modifications are required, revise the protocol or related document and resubmit to the IRB **(Form 2.4)**	Principal Investigator	
7	Check and review revisions and refer to full board for decision	Primary Reviewers	1 working day
8	After board approval, prepare the Approval Letter **(Form 2.10)** to be signed by the Chair and sent to the Principal Investigator	Secretariat	1 working day

9	Keep copies of all documents in the protocol files. Update index **(Form 4.4A and 4.4B)** and the protocol entry in the MMC IRB database	Secretariat	1 working day

Detailed Instructions

2.4.4.1 Secretariat:

A. Receives the Application Form for Protocol Review **(Form 2.1A/B/C)** submitted by the Principal Investigator including the protocol package.
B. Check the completeness of the protocol package using the checklist **(Form 2.2 / 2.4)**.
C. Upon receiving the package, indicates the date and affix staff's signature.
D. Returns the signed acknowledgment form back to the representative of the principal investigators.

2.4.4.2 Member-Secretariat/ Chair

A. Determines if the protocol qualifies for a full board review **(Form 2.6)** based on the criteria.
B. Select primary reviewers with appropriate qualifications (clinician/ scientist with expertise related to the protocol and a non medical person to review the consent form.) An independent consultant may be invited to provide expert opinion. (refer to 2.1.4.5)

2.4.4.3. Review Proper

A. Secretariat sends the protocol files together with the assessment forms **(Form 2.7A, 2.7B and 2.8)** to the primary reviewers/ independent consultant for review
B. Primary reviewers are made aware of the due date for submitting back the results of the review (accomplished checklists) and the protocols to the IRB Secretariat. Turn around time: 3 working days
C. Protocol Review is conducted as described under section 2.2 "Protocol Evaluation". Primary reviewer indicates the date and affix his signature in the decision forms **(Form 2.7B and 2.8)**.
D. Completed forms are submitted to the Secretariat together with the protocol documents. Secretariat only accepts completely filled out forms **(Form 2.7B and 2.8)**.
E. If primary reviewers cannot be present during the scheduled full board review, the accomplished assessment forms with comments and recommendations are

returned to the IRB Secretariat before the full board The Chair or member-secretary may speak in behalf of the absent reviewer.

2.4.4.4 Full Board Meeting

A. The protocol is scheduled for presentation, discussion and decision for approval during the next full board meeting.

B. Schedule

- Regular MMC IRB meeting is conducted every third Tuesday of the month. The meeting starts at 12:30 pm and ends at 3:00pm, depending on the number of documents to be reviewed.
- A special meeting may be held upon the decision of the chair of the MMC IRB.
- One (1) week notice shall be given to all MMC IRB members on the schedule of the meeting. The agenda shall also be provided with this notice.

C. Attendance and Quorum

- Only the members of the MMC IRB and IRB Secretariat are allowed to attend the meeting unless otherwise specified.
- The principal investigator or designated representative and independent consultant/expert reviewer are invited to be present on the particular portion of the meeting when specific protocol is reviewed.
- For Makati Medical Center investigator-initiated protocols, a member of the Department Research Committee shall sit in the full board meeting as a consultant to explain technical issues.
- For non-Makati Medical Center proposals, the IRB may request for comments/ approval from other IRB independent consultants as expert reviewer to provide additional inputs as deemed necessary.
- Before the conduct of the meeting and review of every protocol or report, the chair determines the quorum and conflict of interest.
- Meeting may be suspended or terminated early once quorum is lost.

D. Meeting Proper

- One of the primary reviewers presents the summary of the protocol and discusses his assessment with the Board with respect to scientific concerns, ethical matters. and informed consent (when applicable)
- The principal investigator is invited during the portion of the meeting where the protocol is being discussed to clarify issues and listen to the review of the primary reviewers
- Chair facilitates the discussion and summarizes the issues if any.
- Chair may give a 5 to 10-minute break to maintain the integrity of quorum.
- The members are encouraged to refrain from leaving at any time during a review to maintain the quorum.
- Discussion during the meeting are organized into 2 parts: Technical and Ethical Issues and 2) Informed Consent Form
- Decision points are as follows: Approved, Minor revision, Major revision, Disapproved, Pending Decision for Protocol and Informed Consent Form.
- Final decision for the protocol is made through voting. The chair will ask the board members by show of hands and in which the decision will favor the majority. Record of voting is shown (i.e., for, against, abstention);
- The Secretariat minute taker records the decision by marking the appropriate block in the assessment form as follows: Approved, Minor revision, Major revision for resubmission, Disapproved or Pending Decision.
  - Include comments, discussion points, recommendations and reasons for the decision or disapproval
- If the protocol is approved, the MMC IRB determines the frequency of continuing review.

2.4.4.5 The Secretariat sends an Action Letter/ Approval Letter (**Form 2.10**) with a list of approved documents to the principal investigator.

A. Letter **(Form 2.10)** contains identification of the document approved with version numbers and dates, the frequency of continuing review and the responsibilities of the principal investigator throughout the course of the study.
B. If the decision is not to approve the study, the Secretariat immediately notifies the principal investigator in writing about the decision and the reason for not approving the study **(Form 2.9)**.
   - If the principal investigator wishes to appeal the IRB decision, he/she may do so through a written request submitted to the MMC IRB.

2.4.4.6 For Resubmission

A. If the decision is to revise and resubmit modifications to any of the documents, the Secretariat prepares the Notice of Decision through a letter to the Principal Investigator and identifies the necessary revisions. After which, the turn around time stops and resumes after resubmission is given.

B. The Principal Investigator resubmits the revised documents to MMC IRB **(Form 2.4 and 2.9)**. within 12 calendar days after the release of the Notification of IRB Decision **(Form 2.9).** If the resubmission is not provided 6 months from the release of the Notification of IRB Decision (Form 2.9), the research is considered inactive.

2.4.4.7 Protocols that require revision and resubmitted are sent back to the primary reviewers by the Secretariat for re-evaluation.

A. Reviewers evaluate the document that requires revision.

B. Primary reviewers recommend approval if the issues are satisfactorily addressed.

C. Resubmissions are included in the next full board meeting for discussion and decision.

2.4.4.8 Principal Investigator is informed of the board decision. **(Form 2.9)** by the Secretariat by sending the Notice of Decision and Letter of Approval

2.4.4.9 For sponsored protocols, the Clinical Trial Agreement is facilitated by the Secretariat,

2.4.4.10 All meeting deliberations, decision regarding a protocol are noted in the meeting minutes and copies of the assessment forms are kept in relevant sections of the protocol file.

The IRB database protocol index **(Form 4.5)** and tracker **(Form 4.4A and 4.4B)** are to record the decision.

All information regarding the date of the Makati Medical Center IRB decision, date when decision was written and signed by the Chair, and date when it was delivered to the principal investigator, is entered in the IRB database.

2.5 Expedited Review by SPARES

2.5.1 Purpose

To describe the procedures for the review of protocols that qualify for expedited review

2.5.2 Scope

This SOP applies to the review and approval of study protocols with minimal risk to study participants and minor revisions in the protocol or informed consent.

This also applies to protocols initially reviewed under full board for minor modifications and was decided for resubmissions to be reviewed by SPARES as expedited

2.5.3 Responsibility

It is the responsibility of the Secretariat to manage the document submission, send protocol documents to the primary reviewers, refer the protocol to the primary reviewers for discussion and decision, arrange and facilitate the SPARES meeting, communicate the review results to the Principal Investigator, keep copies of the documents in the protocol files and update the protocol entry in the IRB database.

It is the responsibility of primary reviewers to assess and make recommendations for appropriate reaction any protocol that qualifies for the expedited process. The same assessment forms used for full board review should be used to evaluate the scientific and ethical merits of the protocol **(Form 2.7A, 2.7B and 2.8)**.

Process Flow/ Steps

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive the submitted documents, check for completeness and forward to the Chair or Member-Secretary **(Form 2.1, 2.2, 2.4 and 2.5)**	Secretariat	1 working day
2	Determine that the protocol is for expedited review **(Form 2.6)** and assigns reviewers.	Member-Secretary Chair	1 working day 1 working day
3	Conduct expedited review, attend SPARES meeting and submit the decision to the Secretariat **(Form 2.7A, 2.7B, 2.7C and 2.8)**	Reviewers	3 workdays
4	Communicate the decision for approval or revision to the Principal Investigator **(Form 2.9)**	Secretariat	1 working day
5	If modifications are required, revise the protocol or related document and resubmit to the IRB **(Form 2.3/ 2.7C)**	Principal Investigator	1 working day
6	Review revisions and recommend if for approval **(Form 2.7C)**.	Reviewers	1 working day
7	Prepare an Approval Letter to be signed by the Chair and sent to the Principal Investigator **(Form 2.10)**.	Secretariat	1 working day
8	Report results of expedited review to full board	Secretariat	1 working day
9	Keep copies of related documents in the protocol file.	Secretariat	1 working day
10	Update the IRB database, protocol tracker (**Form 4.4A and 4.4B**) and index.	Secretariat	1 working day

Detailed instructions

2.5.4.1 Secretariat

A. Receives the application documents submitted by investigators **(Form 2.1A/B/C)**.
B. Checks items received using the checklist as guide **(Form 2.2 and 2.4)**.
C. Signs a copy of the application form (**Form 2.1A/B/C)** to acknowledge receipt of the documents and return a copy to the principal investigator or a duly designated representative.

2.5.4.2 Member-Secretariat/Chair determine that the protocol is for expedited review (Form 2.6) based on the criteria.

Select primary reviewers with appropriate qualifications (clinician/ scientist with expertise related to the protocol and a non-medical person to review the consent form.) An independent consultant may be invited to provide expert opinion. (Refer to 2.1.4.5)

A. Send the protocol files together with the assessment form **(Form 2.7A, 2.7B and 2.8)** to the primary reviewers/ independent consultant.
B. Note on the cover letter the due date for submitting the results of review (accomplished checklists) and sending the protocols back to the IRB Secretariat.

2.5.4.3 Primary reviewers carry out the expedited review on the protocol and related documents (patient information sheet, consent form, advertisements, etc.) as described under section 2.2 “Protocol Evaluation”

- Secretariat arranges the schedule and facilitates the SPARES meeting for the month
- Primary reviewers/ SPARES reviewers for the month meets and makes a decision
- Principal investigator maybe invited during the meeting for any clarification

2.5.4.4 Protocol Evaluation Decision (Please refer to Section 1.1.9.4 of MMC IRB SOP Chapter 1)

A. If the study is approved,

1) Secretariat sends an Action Letter/ Approval Letter (**Form 2.10**) with a list of approved documents to the principal investigator.
2) Letter contains identification of the documents approved with version numbers and dates, the frequency of continuing review and the responsibilities of the principal investigator throughout the course of the study.

B. If the protocol is recommended for disapproval, the Secretariat reports the recommendation during the Full Board meeting for decision. Secretariat notifies the principal investigator in writing about the full board decision and the reason for not approving the study (**Form 2.9**)
   1) If the principal investigator wishes to appeal the IRB decision, he/she may do so through a Letter of Intent submitted to the MMC IRB Chair (please refer to section 1.1.9.5 in MMC IRB SOP Chapter 1).

C. If the decision is to revise and resubmit modifications to any of the documents, the Secretariat prepares a letter to the Principal Investigator and identifies the necessary revisions to the documents before resubmission to the MMC IRB **(Form 2.4 and 2.9).**
   At this point, the turn around time stops until the protocol is resubmitted.
   The Principal Investigator is required to resubmit study protocol 12 calendar days after the release of the Notification of IRB Decision **(Form 2.9).**
   A reminder letter is provided to the Principal Investigator who fails to resubmit within 12 calendar days. If the resubmission is not provided 6 months from the release of the Notification of IRB Decision (Form 2.9), the research is considered inactive.

D. If the protocol is for major revision, the resubmission undergoes full board review. The following are the criteria for major revisions which may be issues related to, but not limited, to the following:
   1. No equipoise
   2. Nature of Study
   3. Major Issues related to Vulnerability of Subjects
   4. Objectives or methodology are not appropriate
   5. Major criteria in evaluation not satisfactory.
   6. Risk-benefit assessment is not appropriate

2.5.4.5 If modifications are required, Principal Investigators revise the protocol or related document and resubmit to the MMC IRB.

2.5.4.6 Resubmitted protocol and documents are sent to the primary reviewers for evaluation.

A. Reviewers evaluate the document.
B. Primary reviewers recommend approval if there are no issues.

2.5.4.7 Decision is communicated to the principal investigators **(Form 2.9)**.

A. Turnaround time to communicate board decision is four weeks from the time the protocol was submitted.
B. Dated received copy of the approval letter is kept in file.

2.5.4.8 Approved Expedited protocols are reported to full board for information purposes.

2.5.4.9 All meeting deliberations, decision regarding a protocol are noted in the meeting minutes and copies of the assessment forms are kept in relevant sections of the protocol file.

2.5.4.10 The MMC IRB database, protocol index and tracker are to record the decision.

- All information regarding the date of the Makati Medical Center IRB decision, date when decision was written and signed by the Chair, and date when it was delivered to the principal investigator, is entered in the IRB database.

2.6 Review of a Medical Device Protocol

2.6.1 Purpose

To describe procedures in the review of medical device protocols submitted to the IRB.

2.6.2 Scope

This SOP provides instructions for review and approval of medical device protocols intended for human participants submitted to the Makati Medical Center IRB.

Medical device protocols are reviewed through the same expedited or full board procedures depending on the level of risks involved in the study. An investigational new device is given a Significant Risk (SR) or Non Significant Risk (NSR) classification by the regulators in the sponsor country. (Refer to Appendix: Guide for Study Device Classifications). This information should be provided by the sponsor to the IRB. The IRB should make provisions to minimize the risks to human participants during review of the protocol and related documents.

2.6.3 Responsibility

It is the responsibility of the IRB members to review medical device protocols in accordance with international and national guidelines and regulations.

2.6.4 Process Flow/Steps

N	ACTIVITY	RESPONSI	TIMELINE
1	Receive the submitted documents, check for completeness and forward to Member-Secretary and Chair **(Form 2.1, 2.2, 2.4, 2.5)**.	Secretariat	1 working day
2	Determine if the protocol is for Expedited or Full Board review depending on Significant Risk or Non Significant Risk determination **(Form 2.6)**. Assign primary reviewers to review	Member-Secretary Chair	1 working day 1 working day
3	Conduct the review using the assessment forms (**Form 2.7A, 2.7B, 2.7C, 2.8 and 2.11**) and submit the decision/ recommendation to the	Primary Reviewers	3 working day

4a	Expedited Review: Communicate the decision from expedited reviewers for approval or revision **(Form 2.9 and Form 2.10)** to the Principal Investigator.	Secretariat	1 working day
4b	Full Board Review: Include the protocol in the meeting agenda **(Form 4.1)** for discussion and decision by full board. Communicate to te Principal Investigator the decision of the Board after full board meeting	Secretariat	2 working days
5	If modifications are required **(Form 2.9)**, revise the protocol or related document and resubmit **(Form 2.1, 2.4, 2.7A and 2.7C)** to the IRB.	Principal Investigator	
6	Receive revised protocol and distribute to primary reviewers	Secretariat	1 working day
7	Check and review revisions. **(Form 2.7C)**	Primary Reviewers	1 working day
8	Prepare an Approval Letter to be signed by the Chair and sent to the Principal Investigator. **(Form 2.10)**	Secretariat	1 working day
9	Keep copies of related documents in the files. Update the protocol index, tracker and database	Secretariat	1 working day

Detailed Instructions

2.6.4.1 The Secretariat receives the submitted complete set of documents and forwards to the Member-Secretary and Chair (**Form 2.1, 2.2, 2.4, 2.5**).

2.6.4.2 Member - secretary and Chair checks the information/communication from the principal investigator related to the Significant Risk (SR) or Non Significant Risk (NSR) determination by regulators (FDA) from the sponsor country. The protocol is assigned to expedited review or full board review depending on the risk assessment.

Unless the FDA has already made a risk determination for the study, the **convened** full Institutional Review Board (IRB) must review the sponsor's Significant Risk or Non Significant risk determination for every investigational medical device study reviewed and modify the determination if the IRB disagrees with the sponsor.

For a device study to be eligible for expedited review, it must either be: 1. exempt from IDE requirements or 2. previously determined to be an NSR study by the FDA or full IRB **AND** present no more than minimized risk to the subject (probability and magnitude of harm or discomfort are not greater than, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

Primary reviewers with appropriate expertise are assigned to review the protocol and related documents. It is advisable that a bioengineer with appropriate experience related to the medical device together with a medical doctor with related clinical experience are assigned to review the protocol while a lay person/ non medical member reviews the consent form.

2.6.4.3 The Primary Reviewers use the MMC IRB Evaluation forms **(Form 2.7A, 2.7B, 2.8, and 2.11**. When reviewing a medical device protocol, the reviewer should also consider the following **(Device Assessment Form 2.11)**:

A. Proposed investigational plan (use of the device in the study)
B. Description of the device/ Product information including handling and storage requirements.
C. Copies of all labeling for investigational use
D. Reports of prior investigations conducted with the device
E. FDA Approval, IDE number
F. Risk assessment determination for new investigational device (Significant Risk or Non Significant Risk) and the rationale
G. Choice of comparator and justification (if applicable)
H. Summary of the necessary training and the experience needed to use the investigational device.
I. Device control, access and accountability.
J. List of additional procedures (example: surgery), medical device or medication to be used as part of the investigational study.
K. Risk-benefit assessment
L. Safety and effectiveness/ performance assessments
M. Prohibition against promotion or commercialization of, and certain other practices relative to, investigational devices.

N. References.

2.6.4.4a **For Expedited review:** Primary reviewers review the protocol and make a decision. Decision is reported in next full board meeting. (Please refer to Section 1.1.9.4 of MMC IRB SOP Chapter 1)

2.6.4.4b **For Full board review:** a decision is made after discussion during the meeting. (Please refer to Section 1.1.9.4 of MMC IRB SOP Chapter 1)

If an IRB determines that an investigation involves an SR device that the sponsor thought was an NSR device, it must notify the investigator and, if appropriate, the sponsor. If this occurs, the sponsor may not begin the investigation until an FDA approval is obtained.

2.6.4.5 If the protocol is for revision, the recommendations are communicated to the Principal investigator for resubmission **(Form 2.9)**.

At this point, the turn around time is stopped and resumed only after resubmission.

2.6.4.6 Documents are resubmitted **(Form 2.1, 2.4, 2.7A and 2.7C)** are received by the Secretariat and distributed back to the primary reviewers.

2.6.4.7 Primary reviewers checks the revisions through expedited channel for minor revision or sent to full board for review of major revisions.

2.6.4.8 As soon as approved, the Notice of Decision and Letter of Approval **(Form 2.10)** is prepared, signed by the Chair and communicated to the principal investigator. The frequency of continuing review is indicated in the approval letter.

2.6.4.9 The relevant documents are kept in the protocol file. Entries on the protocol database, tracker, and index about the protocol are updated accordingly.

2.7 Subcommittee PAnels for Minimal Risk REsearch ProtocolS (SPARES)

2.7.1 Purpose

To describe the mechanics of the Subcommittee PAnels for Minimal Risk REsearch ProtocolS (SPARES)

2.7.2 Scope

This SOP applies to the review and approval or study protocols within the scope of function of the SPARES.

2.7.3 Responsibility

It is the responsibility of SPARES members to review minimal risk protocols to expedite the review which include prospective studies, retrospective studies, chart reviews, simple descriptive studies, surveys or questionnaires, or other protocols involving minimal or no risk to study participants. The subcommittee is assigned as the primary reviewer and also provides oversight and continuing review to post approval monitoring.

2.7.4 Process Flow/ Steps

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Determine based on risk assessment if the study protocol will undergo the expedited review of the SPARES subcommittee or full board	Member-Secretary Chair	1 working day 1 working day
2	Distributes the protocols for review and coordinates schedule and facilitates the SPARES meeting	Secretariat	1 working day
3	SPARES review the protocols for the month and forwards the evaluation forms to the Secretariat	SPARES reviewers	3 working days
4	Conduct of SPARES meeting to decide on the protocols	SPARES reviewers	1 working day
5	Sends Notice of Decision to Principal Investigator and reports decisions on SPARES protocols to the next full board meeting. Updates database and index	Secretariat	1 working day

Detailed instructions

2.7.4.1 Member-secretary recommends and IRB chair approves the protocol assigned under SPARES and the respective SPARES reviewer assignments.

The criteria for assigning in the SPARES are:

A. Prospective research with minimal risk initiated by trainees
B. All protocols falling under EXPEDITED review process
C. Retrospective studies
D. Chart reviews
E. Simple descriptive surveys or questionnaires.
F. Other protocols involving minimal risk, subjects or participants.

2.7.4.2 Secretariat coordinates with the assigned SPARES subcommittee chair and schedules a meeting with all members once a month preferably on the 4th week or 1st week of the month.

Principal investigators may be invited during the meeting to clarify matters about the protocol.

2.7.4.3 Each SPARES reviewer is given 3 working days to review the protocols.

2.7.4.4 Protocol deliberation and decision is reached during the SPARES meeting.
The decision algorithm of the MMC IRB review process is as follows

A. Approved.
B. Minor modification (the resubmission of the protocol will undergo expedited review).
C. Major modification (the resubmission of the protocol will undergo full board review or another SPARES meeting).
D. For Full Board Discussion
E. Pending Decision

2.7.4.5 Secretariat sends Notice of Decision to Principal Investigator and reports decisions on SPARES protocols on the next full board meeting.

If the recommendation is for disapproval, the decision is done during the full board meeting after deliberation.

IRB database, index and tracker are updated accordingly.

2.8 Review of Resubmission

2.8.1 Purpose

To describe the procedures for the review of resubmissions.

2.8.2 Scope

This SOP applies to the review and approval of resubmitted documents (i.e, protocols, informed consent forms, and answers to IRB inquiries) and other revisions made on the study protocol prior to the initial approval.

2.8.3 Responsibility

It is the responsibility of the Secretariat to manage the document submission, send protocol documents to the primary reviewers, refer the protocol to full board meeting for discussion and decision, communicate the review results to the Principal Investigator, keep copies of the documents in the protocol files and update the protocol entry in the IRB database.

It is the responsibility of the primary reviewers to review and provide recommendations on the resubmissions.

The principal investigator is required to resubmit the study protocol with the response to the IRB inquiries 5 working days after the release of the Notification of IRB Decision **(Form 2.9).** If the resubmission is not provided 6 months from the release of the Notification of IRB Decision (Form 2.9), the research is considered inactive.

2.8.4 Process Flow/ Steps

NO	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive the submitted documents (with **Form 2.1, 2.7A, and 2.7C)** check for completeness of the requiremetns **(Form 2.4)** and forward to the Member-Secretary and IRB Chair ⬇	Secretariat	1 working day
NO	**ACTIVITY**	**RESPONSIBILITY**	**TIMELINE**

2	Determine the type of review **(Form 2.6)** for the resubmission according to the decision **(Form 2.9)** made during the previous review. ⬇	Member-Secretary Chair	1 working day 1 working day
3	Distribute the documents to the originally assigned reviewers. ⬇	Secretariat	1 working day
4	Review the resubmission and submit the evaluation form to Secretariat For full Board review, final decision is determined during the full board meeting ⬇	IRB Members/ Reviewers	1 working day
5	Prepare the Notice of Decision and provide a signed copy of the Notification of IRB Decision **(Form 2.9)** and Approval Letter **(Form 2.10)** to the principal investigator**.** ⬇	Secretariat	1 working day
6	Keep a copy of the approved protocol in the protocol folder and update the IRB database, protocol tracker (**Form 4.4A and 4.4B**) and index.	Secretariat	1 working day

Detailed Instructions

2.8.4.1 The Secretariat receives the documents for resubmission including the required forms **(Form 2.1, 2.7A, and 2.7C).** Using the List of Requirements for Resubmission **(Form 2.4),** the Secretariat checks for completeness.
As soon as resubmission documents are complete, the turn around time for approval restarts

2.8.4.2 Member-Secretary recommends the type of review for the resubmission according to the decision **(Form 2.9)** made during the previous review. The Chair approves the recommended type of review.

2.8.4.3 Received documents for resubmission review are forwarded to the original reviewers.

For full board review, Secretariat includes the resubmission in the Agenda of the next full board meeting.

The Principal Investigator is no longer required to attend the meeting. The Independent Consultant is invited to attend when needed.

2.8.4.4 Reviewers are given one (1) working day to review the resubmission. Evaluation Forms are forwarded to the Secretariat.

For resubmission scheduled for full board review, during the IRB meeting, the board members and reviewers deliberate on the resubmission.

The reviewers arrive at a decision – Approval, Minor Modification, Major Modification, Disapproval and Pending Decision.

2.8.4.5 Secretariat prepares the signed Notice of IRB Decision **(Form 2.9)** and the Approval Letter **(Form 2.10)** (when the decision is approval).

For SPARES review, the SPARES Chair signs the Notification of IRB Decision **(Form 2.9).** This is noted by the IRB Chair.

For the full board and expedited review, the Chair signs the Notification of IRB Decision **(Form 2.9)** or the Approval Letter **(Form 2.10).**

Secretariat provides the principal investigator with the copy of the Notification of IRB Decision **(Form 2.9)** or the Approval Letter **(Form 2.10).**

2.8.4.6 Secretariat files a copy of the related documents (i.e., IRB forms, resubmission, etc.) in protocol folder

Secretariat updates the IRB database, protocol tracker (**Form 4.4A and 4.4B**) and index.

2.9 Policy on Protocol Review for Compassionate Use of Stem Cell Therapy and Others

2.9.1 BACKGROUND: COMPASSIONATE OR EXPANDED ACCESS USE

The Department of Health (DOH) of the Philippines allows administering stem cell therapy under compassionate grounds. While stem cell therapy is generally an unproven therapy for many indications, the DOH recognizes its role in some cancers of the blood and bone marrow, and primary immune-deficiencies treated by autologous or allogenic stem cell transplants. These treatments should only be given by trained professionals working in accredited facilities. When expanded access for a therapy is contemplated, even for individual patient use, the Food and Drugs Administration (FDA) requires institutional review board (IRB) review.

As mandated in FDA Circular # 2013-017 and DOH AO #2013-0012, the Makati Medical Center Institutional Review Board (MMC-IRB) must give its approval for administration of stem cell therapy by the MMC-Cellular Therapeutics Center (MMC-CTC) under compassionate grounds.

The MMC-IRB and its members need to understand and consider other pathways such as “compassionate use” or “expanded access” under which patients outside of clinical trials may receive innovative stem cell-based interventions. Below are some of the circumstances involved:

1. Stem cell interventions not initially amenable to a clinical trials approach
2. Expanded access to investigational stem cell products
3. Off label uses of FDA-approved stem cell products

“Compassionate Use” refers to the treatment of a seriously ill patient using an unapproved agent or modality where no other available treatments are satisfactory. Such use of an investigational drug, biologic or device is allowed only after prior review and approval by the IRB, and in most circumstances, prior approval by the FDA as well. Prior approval is needed even if only one patient is to be treated.

Expanded Access

Treatment INDs or Individual Patient Access to Investigational Drugs/Devices for Serious Diseases - are primarily intended to give seriously ill patients access to experimental drugs or devices where no comparable or satisfactory alternative treatment is available. Although the sponsor is expected to continue conventional clinical trials and pursue marketing approvals with due diligence, expanded access studies involve systematic use of experimental treatments, and with very rare exceptions, require the same review and approval as research.

According to new US FDA policies made effective October 13, 2009, physicians may now request access to investigational drugs and biological products to treat individual patients and intermediate-size patient populations between 10 and 100. Its revised rules for expanded access are intended to "improve access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions who lack other therapeutic options and who may benefit from such therapies."

Physicians can request FDA permission to administer investigational biological products (such as more-than-minimally manipulated stem cells and their derivatives) as long as these products are currently being tested elsewhere in a clinical trial and only if expanded access will not interfere with the conduct of clinical investigations.

Innovative therapies do not aim to produce generalizable knowledge but are aimed primarily at providing new forms of clinical care that have a reasonable chance of success for individual patients with few or no acceptable medical alternatives.

The terms *expanded access*, *access,* and *treatment use* are used interchangeably to refer to use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. The distinction between expanded access and the use of an investigational drug in the usual studies covered under an IND is that expanded access uses are not primarily intended to obtain information about the safety or effectiveness of a drug.

In order to request compassionate use or expanded access for individual patients or intermediate-size patient populations, the MMC-CTC must submit an application that includes the following:

1. the rationale for intended use
2. patient selection criteria
3. a description of the manufacturing facility
4. the method of administration to the patient
5. safety/toxicology information
6. plan of follow-up and monitoring
7. endorsement or letter of support by attending physician/department or section
8. review and approval by the MMC-CTC Subcommittee on Ethics

To render a favorable decision, the IRB must be convinced by the requesting physician or entity:

1. That the **probable risk to the patient from the investigational drug is not greater than the probable risk from the disease or condition**. The patient's physician and the requesting laboratory should make this determination based on the information about the drug available to the physician and the physician's knowledge of the patient's clinical situation.
2. that **the potential benefit justifies the potential risks of the treatment use with the drug and that those risks are not unreasonable in the context of the disease or condition to be treated.**
3. that the patient has a serious or life-threatening disease or condition and no other comparable or satisfactory therapeutic options
4. that providing access will not interfere with development of the drug for the expanded access use
5. that the patient cannot obtain the drug under another IND or protocol e.g., in a clinical study of the drug.

2.9.2 Objectives of Aforementioned Policy

To guide the MMC-IRB in reviewing protocols for diagnostic or therapeutic modalities under compassionate grounds

To identify the criteria that qualifies individuals for such compassionate use

To define the process to render a decision for compassionate use of any diagnostic or therapeutic modality

2.9.3 Scope

This policy applies to all requests for compassionate use of any diagnostic or therapeutic intervention submitted to the MMC-IRB to be conducted at MMC and/or to be performed outside MMC by an affiliated investigator.

The policy is initially developed to guide the IRB on protocols for stem cell therapy. It is expected that the same policy will be applied to other similar requests and protocols.

2.9.4 Responsibility

The Department Heads/ Managers of involved departments and principal investigators ensure the implementation of this policy.

2.9.5 Definition of Terms

Compassionate Use – use of a treatment outside a clinical trial in patients with serious or life-threatening diseases for which no other treatment is available or expected to be effective.

Stem Cell Therapy – a procedure that uses stem cells to treat or prevent conditions and diseases

Standard of Care – intervention generally accepted by experts and health care practitioners. (National Ethical Guidelines for Health Research 2011)

2.9.6 Criteria

These are the specific considerations in the compassionate use of stem cell therapy. The criteria that will allow access to compassionate treatment are:

1. The lack of an effective alternative treatment
2. Danger to the patient's life or serious damage to his or her health or a case of serious disease in rapid progression if no further intervention is done
3. Accountability by the prescribing physician and the director of the Cellular Therapeutics Laboratory

2.9.7 Process Flow/ Step

NO	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive the complete submitted documents (with **Form 2.2, or 2.4**) and forwards to the Member-Secretary and Chair	Secretariat	1 working day
2	Determine the Type of Review as Full Board Review **(Form 2.6)** and assign reviewers	Member-Secretary Chair	1 working day 1 working day

3	Review the protocol documents using the guidelines in reviewing protocols on compassionate use. Submit evaluation to Secretariat ⬇	Primary Reviewers	3 working days
4	Include the protocol in the full board meeting agenda **(Form 4.1)** for discussion to arrive at a decision through full board ⬇	Secretariat / Members	1 working day
6	Prepare the signed Notice of Decision and communicate board decision to the principal investigator **(Form 2.9)** ⬇	Secretariat/ Chair	1 working day
7	Keep copies of all documents in the protocol files. Update index **(Form 4.4A and 4.4B)** and the protocol entry in the MMC IRB database	Secretariat	1 working day

Detailed Instructions:

2.9.7.1 The IRB Secretariat receives the submitted documents **(including Forms 2.1, 2.2, 2.5.2.7A, 2.7B, 2.8).** In addition to the documents specified in Form 2.2, the following are also required:

A. Letter for Intent from the Patient
B. Medical Abstract
C. Endorsement letter from the Attending Physician or an indication that there is no other possible management.
D. Informed Consent Form signed by the patient.
E. Minutes of the Meeting specifying the decision/ recommendation of the Cellular Therapeutics Ethics Committee.

Complete submitted documents are forwarded to the Member-Secretary and Chair for the determination of type of review.

2.9.7.2 Utilizing Form 2.6, the Member-Secretary recommends the type of review the study must undergo and assign primary reviewers. Chair approves the recommendations of the Member-Secretary and signs Form 2.6. Secretariat distributes the protocol package to assigned reviewers

2.9.7.3 The guidelines in reviewing protocols on compassionate use are applied in the evaluation of the study protocols.

Guidelines for Review

In compliance with the Food and Drug Administration (FDA) Circular 2013-0017 issued last 8 July 2013, "all human cells, tissues and cellular and tissue-based products (HCT/P's) are required to be registered under the Philippines regulatory agency." The therapy may only be conducted in accredited and licensed facilities. (FDA Circular No 2013-020)

To qualify for compassionate use, the patient must:

1. Have been given a diagnosis of a likely fatal illness. Examples include COPD, Coronary Artery Disease and Congestive Heart Failure
2. Have written statement from a board-certified physician in the same area of specialty of the likely fatal disease which states that the patient is end stage with an incurable disease, that no other types of care are available or other reasonable alternatives have failed, and the patient's condition is expected to worsen. (ICMS Compassionate Use in Stem Cell Therapies)

Compassionate use or humanitarian use of an investigational treatment is reviewed by an ethical review committee as though it were research. Informed consent should be obtained according to the legal requirements and cultural standards of the community in which the intervention is carried out.

The IRB is responsible for reviewing the following:

1. Ethical aspect of the research and therapy
2. Scientific rationale, design and data collection on safety and efficacy of stem cell and cell based or cellular therapy programs
3. Documentation and reporting of adverse events observed in patients receiving stem cell and cell-based or cellular treatments.

Free and informed consent should be obtained from the recipient of compassionate use prior to the start of the therapy. The informed consent should comply with the following universal ethical standards:

1. Comprehensive informed consent to include all possible benefits, side effects, costs (if any), provisions for withdrawal, plan of follow up and monitoring, and all unknowns

2. Informed consent that should contain safeguards so that consent can be obtained without undue influence
3. A copy of the consent provided to participants or patients, among others.

2.9.7.4 Secretariat, with the approval from the Chair, includes the protocol in the meeting agenda (Form 4.1) for discussion to arrive a decision through full board.

Request is discussed in Full board (with mandatory attendance by a lay member). Decision points are Approved, Major Revisions, Minor Revisions, Disapproved.

2.9.7.5 Secretariat prepares the communication (Form 2.9) to the principal investigator specifying the board decision. Chair signs the notification before sending the document to the Principal Investigator.

2.9.7.6 A copy of the notification (Form 2.9) and all other documents are kept in the protocol files. Secretariat updated the trackers, index (Form 4.4.A, 4.4B and 4.5) and IRB database.

2.10 Clinical Trial Agreement (CTA)

2.10.1 Purpose

To describe the relationship of the Makati Medical Center Institutional Review Board procedures related to the signing process of a Clinical Trial Agreement (CTA). A clinical trial agreement acts as the legal protection of the sponsor, the institution and other individuals involved in the trial.

2.10.2 Scope

A clinical trial agreement is the tripartite contractual agreement between the Sponsor, the Investigator and Institution for clinical trials to avoid FDA compliance actions and later disputes over terms and obligations. A basic fee called Institutional Fee amounting to Php 120,000.00 (net of withholding tax) is applied for review of the agreement – legal and other pertinent issues. The Institutional fee is non-refundable.

The MMC IRB has no oversight functions over a legal agreement between the study sponsor and the institution.

2.10.3 Responsibility

The Chair endorses to the Medical Director the protocols ethically cleared and approved by the MMR IRB.

The Medical Director, representing the Makati Medical Center, signs the clinical trial agreement upon the endorsement of the Makati Medical Center Institutional Review Board Chair and legal review of the legal officer.

2.10.4 Process Flow/ Steps

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive the copies of the CTA and official receipt of payment of the institutional fee. ⬇	Secretariat	1 working day
2	Endorse the CTA to the medical director that the study involved has been ethically approved by the MMC IRB. ⬇	Chair	1 working day

3	Send CTA for legal review and approval of the legal officer.	Medical Director	1 working day
4	Review and approve the CTA.	Legal Counsel	1 working day
5	Sign the CTA and return the CTA to MMC IRB	Medical Director	1 working day
6	Release the CTA to the Principal Investigator/Sponsor/Clinical Research Center, keep a copy of the CTA on file. The protocol index and database are updated.	Secretariat	1 working day

Detailed Instructions:

2.10.4.1 The secretariat receives seven (7) original copies of the Clinical Trial Agreement and a copy of the receipt of the institutional fee payment from the Principal Investigator/Sponsor/Clinical Research Center.

The institutional fee is Php 120,000.00 (net of withholding tax), payable to "Makati Medical Center". An official Statement of Account for the institutional fee may be requested from the Secretariat Staff to process the payment.

For cash/check payments, the Investigator/Member of the Study Team should directly pay to the MMC Cashier 3 located on the Ground Floor of the MMC Tower 1 and ask the cashier to credit payment to Institution's Cost Code 6000000. The Official Receipt must reflect "Institutional Fee" under particulars, and a copy of the receipt is submitted to the IRB Secretariat as one of the requirements for CTA submission.

For payments made via wire transfer, the Investigator/Member of the Study team should forward the wire transfer details to the IRB Secretariat via email as one of the requirements for CTA submission. The IRB Secretariat will then facilitate confirmation of payment from Finance. Once confirmed, a printed copy of the wire transfer payment and confirmation from Finance must be submitted to the MMC Cashier 3 located on the Ground Floor of the MMC Tower 1, for issuance of Official Receipt and ask the cashier to credit payment to the Institution's Cost Code 6000000. The Official Receipt must reflect

"Institutional Fee" under particulars, and the IRB Secretariat gives a copy of the receipt to the Investigator/Member of the Study Team.

2.10.4.2 The Chair endorses the CTA to the Medical Director if the study involved has been ethically approved by the MMC IRB.

2.10.4.3 The medical director sends the CTA to the legal counsel for legal review.

2.10.4.4 The legal counsel reviews and approves the CTA.

2.10.4.5 The medical director signs the CTA and returns the CTA to MMC IRB.

2.10.4.6 The MMC IRB Secretariat returns the signed copies of the CTA to the Principal Investigator/Sponsor/Clinical Research Center.

2.10.4.7 A copy of the CTA is kept on file. The protocol index and database are updated.

2.11 Single Joint Research Ethics Board (SJREB) Review

2.11.1 Purpose

To describe the relationship of the Makati Medical Center Institutional Review Board procedures related to the Single Joint Research Ethics Board (SJREB).

2.11.2 Scope

This SOP is applied to all protocols submitted for parallel review to SJREB and MMC IRB. Standard Operating Procedure for protocol review still apply.

SJREB is a joint review mechanism for research protocols that will be conducted in at least three (3) sites in the Philippines. SJREB review is required for Philippine Health Research Ethics Board (PHREB) accredited Research Ethics Committees (RECs) of DOH hospitals. It is also applicable to non-DOH Research Ethics Committees (RECs) that will accept the results of the SJREB review and will agree and abide with the procedures that the SJREB follows. Refer to *Standard Operating Procedures for Single Joint Research Ethics Board (SJREB),* "SOP 1 Authority, Composition and Structure of SJREB."

2.11.3 Responsibility

It is the responsibility of the Makati Medical Center Institutional Review Board (MMC IRB) to participate in the SJREB review.

For non-DOH hospital RECs, such as MMC-IRB, SJREB decision is recommendatory and MMC IRB holds the option to accept or reject SJREB decision.

2.11.4 Process Flow/ Steps

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receives parallel submission of protocol to SJREB and MMC IRB. Checks completeness of protocol package and assigns protocol number in database.	Secretariat	1 working day

	Files the documents in the active protocol folder and prepares corresponding index and tracker. Uploads the protocol package in the database		
2	Provides a letter of intent to SJREB to specify the IRB's interest in participating in the joint review of the submitted protocol.	Secretariat	1 working day
3	Receives invite from SJREB for the joint review of the submitted protocol and informs the IRB Chair. Distributes protocol package to IRB chair (or designate) and assigned SPARES reviewers	Secretariat	1 working day
4	Conduct a preliminary review of the protocol prior to SJREB review meeting and appoints representative to SJREB meeting.	IRB Chair (or designated member) and SPARES committee assigned for the month	3 working days
5	Presents all issues identified during the SJREB Meeting	IRB Chair or the designated representative	1 working day
6	Receive communications (e.g., status of the review, approval letter, etc.) from SJREB	Secretariat	1 working day
7	Review of protocol with decision from SJREB and report during the next IRB Full Board meeting	IRB Chair (or designated member) and SPARES committee assigned for the month	1 working day

8	Communicate the decision of the review to the Principal Investigator	Secretariat	1 working day
9	Keep copies of the protocol and protocol-related documents in the protocol file including SJREB meeting minutes	Secretariat	1 working day
10	Update the IRB database, protocol tracker (**Form 4.4A and 4.4B**) and index.	Secretariat	1 working day

Detailed Instructions

2.11.4.1 Receive parallel submission of protocol documents to SJREB and MMC IRB and refer to the following:

A. *Standard Operating Procedures for Single Joint Research Ethics Board (SJREB), "*SOP 2 on Joint Review of Initial Submission"*; and*

B. *MMC IRB SOP* "Chapter 2 Section 2.1 Protocol Submission".

2.11.4.2 MMC IRB submits a letter of intent to SJREB to join in the deliberation by the SJREB. A membership list with Curriculum Vitae is submitted to SJREB. The participating Research Committee identifies the representative qualified to do scientific and ethical review for various types of protocols.

2.11.4.3 Sites that are selected by the sponsor for the conduct of multi-site researches are invited to send a representative to participate in the review during the SJREB meeting. SJREB sends invite for the scheduled meeting.

2.11.4.4 All protocols for Single Joint Review undergo preliminary review by the IRB Chair (or designated member) and SPARES committee assigned by the month. There is a quorum of at least two (2) reviewers. An Independent Consultant may be request to join at the discretion of the IRB Chair. The preliminary review follows the SOP Chapter 2 Initial Protocol Review and Approval.

2.11.4.5 All issues identified are presented by the IRB Chair or the designated representative in the SJREB meeting.

2.11.4.6 Secretariat is updated of the status of the Single Joint review of the protocol. SJREB minutes of the meeting is provided and filed in the protocol folder.

The Joint Review is conducted for the initial review and renewal of approval of the researches.
MMC IRB retains review functions related to post approval submissions.
IRB accepts the decision of the SJREB unless there are ethical issues that need to be addressed.

2.11.4.7 Proceedings of the review are similar to the conduct of the Full Board (Section 2.5) or the SPARES review (Section 2.7).

2.11.4.8 Secretariat prepares the communication to inform the Principal Investigator of the review decision. IRB Chair signs the communication (Form 2.9 or Form 2.10).

2.11.4.9 Secretariat keeps the protocol and all protocol-related documents in the protocol file.

2.11.4.10 Secretariat updates the IRB database and protocol tracker (Form 4.4A and 4.4B) and index.

2.12.1 Objectives:

A. To comply with the Philippine Health Research Ethics Board (PHREB) Resolution No. 20-001 Series of 2020 on the Review of Research Proposals on COVID-19.
B. To minimize health risks and safeguard the welfare of administrative staff, members of the Makati Medical Center- Institutional Review Board (MMC-IRB), reviewers and investigators submitting the protocol.
C. To provide guidelines for the conduct of research ethics review through electronic means.

2.12.2 Extent of distribution

The departments/ division involved in the review of research protocols.

2.12.3 Scope

This policy applies to all consultants, fellows, residents, medical interns, pharmaceutical companies, healthcare professionals and other (affiliated) investigators who plan to conduct researches subject for the review and approval of the MMC-IRB, MMC-IRB Secretariat Staff and MMC IRB Members. This includes the process from the online submission of the research proposal to the review of the post-approval submissions.

Definition of Terms:

Philippine Health Research Ethics Board (PHREB)	-	The national policy making body in health research ethics in the Philippines.
PHREB Resolution No. 20-001 Series of 2020 on the Review of Research Proposals on COVID-19	-	An ad referendum released by PHREB on 13 April 2020 authorizing all Research Ethics Committees regardless of accreditation to suspend application of pertinent provisions of Standard Operating Procedures necessary to conduct online meetings to review research during the COVID-19 pandemic.
COVID-19		Coronavirus disease; defined by the World Health Organization as an infectious disease "caused by a newly

<table>
<tr><td></td><td></td><td>discovered coronavirus spreads primarily through droplets of saliva or discharge from the nose when an infected person coughs or sneezes”’ imposing limitations in human movement.</td></tr>
<tr><td>Exempted from review</td><td></td><td>Protocol submissions that are exempted for review are those that are under the following exemption criteria:
<table>
<tr><th>EX</th><th>EXEMPTION CRITERIA</th></tr>
<tr><td>1</td><td>Study that does not involve human participants nor identifiable tissue, biological samples and data</td></tr>
<tr><td>2</td><td>Study design is meta-analysis and/or systemic with identifiable data</td></tr>
<tr><td>3</td><td>Case Reports</td></tr>
<tr><td>4</td><td>Study with less than minimal risk or harm</td></tr>
<tr><td>5</td><td>Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests</td></tr>
</table></td></tr>
<tr><td>Principal Investigator</td><td></td><td>The main proponent of the research at the site tasked in conducting and overseeing protocol activities in compliance with vital research guidelines.</td></tr>
<tr><td>Protocol Screening</td><td></td><td>A process of determining type of review and assigning reviewers.</td></tr>
<tr><td>Designated Staff of Research Team</td><td></td><td>An administrative staff that is part of the research team that is sometimes delegated to submit documents or inquire protocol status updates to IRB.</td></tr>
<tr><td>Clinical Research Officer/Assistant</td><td></td><td>A clinical staff that is part of the Clinical Research Organization research team that are delegated to submit protocol documents or inquire status updates with regards to IRB operations, settlement of review fees and setting up contracts with MMC and MMC-IRB.</td></tr>
<tr><td>Coding</td><td></td><td>The process of assigning the MMC-IRB code to an initial protocol submission package.</td></tr>
<tr><td>Electronic Log Book</td><td></td><td>A log consisting of all submissions accepted within a day, with information as to the date when documents are received, submission type, name of sender and name of staff who received the document.</td></tr>
</table>

Electronic Master list Database		A master list database found inside the MMC intranet containing basic information of particular research protocol; only the Secretariat staff has access to edit and print the contents of the database
Electronic Protocol Folder		A folder inside a secured internet-based cloud that contains all submitted protocol documents.
Official email		The account issued by Makati Medical Center for IRB use in communicating confidential information and storing documents that are part of a protocol package.
Type of Review		The classification of the review of a submission whether for full board or expedited based on a defined criterion
Primary Reviewers		A small group of IRB members assigned to present the protocol before the Board and provide initial assessment of the technical and ethical soundness of the protocol package.
Independent Consultants		Expert reviewer; individuals that are experts in a particular field who are invited to evaluate the technical and ethical soundness of the protocol that require such expertise in addition to those available within the MMC-IRB
Virtual Meetings		Meetings done through the use of a secured online platform to replace the need for the physical presence of members and staff during meetings.
IT Host		An IT staff designated to assist departments in scheduling and facilitating meetings. The IT host also safeguards security of the online meeting room.
Virtual Conference Reservation Application		A Microsoft application developed by the IT team to schedule meetings using the licensed accounts owned by MMC.
ZOOM		A “cloud-based video conferencing’’ application.
Meeting ID		A log-in detail required in joining a virtual meeting via ZOOM.

Meeting Password		A log-in detail required in joining a virtual meeting via ZOOM which also provides security in an online meeting room.
Visual Aids		Includes the PowerPoint presentations of each initial protocol submission for review, agenda of the meeting and discussion of other matters.
Quorum		The minimum number of IRB members that must be present during meetings to make the proceedings valid.
Conflict of Interest		A member or reviewer holds interest on the study reviewed affecting his/her evaluation and protection of study participants.
Agenda of the Meeting		A document containing the meeting flow and a detailed list of protocol submissions for review and other important matters to be discussed in the meeting.
Minutes of the Meeting		A detailed account of the review and decision of protocol submissions.
Approved Protocols		Protocols that acquired approval from the Board and may start with the implementation/conduct protocol activities
Full Board Review		Major revisions of the protocol and informed consent after initial review/ Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/ exclusion criteria, safety issues, etc.)/ Major amendments that change the risk/ benefit ratio/ Major protocol violations/ Progress/ Final reports that deviate from original approval given by the IRB/ Onsite SAEs or SUSARs that may require protocol amendment or reconsent of participants.
Expedited Review		Proposed initial submissions, continuing reviews, protocol amendments and end of study reports that have minor modifications and no significant risk to study participant.
Other Matters		Includes details regarding the next meeting schedules, financial reports and announcements involving seminars, trainings, and invitations for the Board.
Decision letters		Notification of IRB Decision (NOID) and approval letters containing details of the IRB review of the protocol given to the proponents of a research.

2.12.4 Policy Statement

The MMC-IRB shall receive and screen submission of research proposals with complete pertinent requirements as well as post approval documents through electronic means only during the pandemic. Decision for the application of research protocol and post approval monitoring documents is facilitated through email and virtual meetings during a pandemic emergency.

Process Flow Map

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receives and screens for completeness the protocol and pertinent requirements for IRB review via electronic means to the official IRB email address; As soon as complete, Secretariat sends acknowledgement email and starts the turn around time monitoring ⬇	Secretariat	1 working day
2	Assigns permanent code to the protocol submission package and encodes submissions in the electronic log book and electronic masterlist database; electronic files are uploaded in the database and electronic protocol folder ⬇	Secretariat	1 working day
3	Forwards submission package to Member-Secretary ⬇	Secretariat	1 working day
4	Recommends the Type of Review and Primary Reviewers ⬇	Member-Secretary	1 working day
5	Validates and approves the Member-Secretary's recommendation of Type of Review and Primary Reviewers ⬇	Chair	1 working day
6	Updates Database. Distributes electronic protocol package to assigned reviewers. Include in agenda of full board or spares meeting	Secretariat	1 working day

Detailed Instructions:

2.12.4.1 Secretariat checks the completeness of the documents received based on the requirement checklist within one (1) working day upon receipt of the submission. Acknowledgement receipt is sent to the sender and this will start the turn around time of review and approval.

2.12.4.2 Secretariat assigns a permanent MMCIRB code to the submission package. Complete submissions are entered into the electronic log book and electronic masterlist database. Creates an electronic folder inside the MMC-IRB OneDrive to contain all documents in the submission.

2.12.4.3 IRB Secretariat Staff sends the protocol submission package to the Member-Secretary via email to recommend appropriate type of review and assignment of primary reviewers.

2.12.4.4 Member-Secretary determines and recommends the type of review based on defined criteria and assigns primary reviewers

2.12.4.5 Secretariat forwards the electronic protocol package and recommendation of Member-secretary to the IRB Chair for review and approval. Chair approves/gives suggestions or corrections to the Member-Secretary's recommendations within one (1) working day upon receipt of the submission.

2.12.4.6 Secretariat includes protocol in the agenda of the next meeting of either the full board or SPARES as determined.

2.12.5 Setting of Online Meeting and Quorum Check

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Schedules the meeting through ZOOM virtual reservation ⬇	Secretariat	1 working day
2	Receives confirmation of successful reservation of online meeting room. ⬇	Secretariat	1 working day
3	Sends notice of meeting for a quorum and coordinates meeting details to the Board ⬇	Secretariat	1 working day
4	Confirmation of attendance in the meeting	Chair, Member-Secretary, and IRB Members	1 working day

Detailed Instructions:

2.12.5.1 Secretariat books an available slot for the online meeting at least one (1) week prior to the standard schedule of IRB review meeting (every 3rd Tuesday of the month for full board review, and depending on the schedule set by the IRB SPARES Chair for expedited review).

2.12.5.2 Secretariat receives a confirmation from IT regarding successful reservation and is given the ZOOM meeting ID and password.

2.12.5.3 Within one (1) working day upon the receipt of confirmation and meeting details, the Secretariat asks the availability of the members of the Board through a quorum check in the official MMC-IRB Viber. Group

2.12.5.4 Within one (1) working day upon receipt of the notice of the meeting, the Chair, Member-Secretary and IRB Members must confirm availability/inform his/her absence on the scheduled meeting.

2.12.6 Preparation of Agenda, Meeting Materials and Submissions for Review

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Collate and organize documents of protocols scheduled for the Full board meeting ⬇	Secretariat	1 working day
2	Draft the meeting agenda for review and approval ⬇	Secretariat	1 working day
3	Reviews and approves meeing agenda ⬇	Member-Secretary Chair	1 working day 1 working day
4	Distribute Agenda to the IRB Members	Secretariat	1 working day

Detailed Instructions

2.12.6.1 Secretariat collects electronic submissions within the 3rd and 4th week of the month to be included in the upcoming meeting agenda.

2.12.6.2 Secretariat drafts the meeting agenda by putting all submissions received within the given period for discussion or information of the IRB. Proposed agenda is submitted to the Member-secretary for review and approval no later than the second week of the month

2.12.6.3 Member- Secretary and IRB Chair reviews and approve the proposed meeting agenda

2.12.6.4 Agenda is distributed to the members within two (2) working days upon receipt of the final draft of the agenda from the Chair

2.12.7 Preparation of Meeting Minutes

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Organize and document the meeting procedures and the items taken up based on the meeting agenda (Form 4.1)	Secretariat	1 working day
2	Preparation of the draft of live minutes of the meeting	Secretariat	1 working day

Detailed Instructions

2.12.7.1 Organize and document the meeting procedures and the items taken up based on the meeting agenda (Form 4.1)

2.12.7.2 Preparation of the draft of live minutes of the meeting (Form 4.2).

2.12.8 Distribution of Submissions for Review

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Upload the soft copy of the files for review	Secretariat	1 working day
2	Create a soft copy of folders containing the protocols for review.	Secretariat	1 working day
3	Send the protocols to the designated reviewers in a zip folder.	Secretariat	1 working day

Detailed Instructions

2.12.8.1 Secretariat uploads the soft copy of the files for review (initial proposal, SAEs, post approval monitoring).

2.12.8.2 Secretariat creates a folder in the computer containing the protocols for review.

2.12.8.3 Secretariat sends the protocols to the designated reviewers in a zip folder.

Online Full Board Meeting (Before the meeting)

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Contact IT to prepare a schedule for a zoom meeting. Send calendar invites ⬇	Secretariat	1 working day
2	Prepare the Meeting Agenda for the month. ⬇	Secretariat	1 working day
3	Prepare the Minutes of the meeting. ⬇	Secretariat	1 working day
4	Upload, prepare, and send the soft copy of the files that will be distributed to the reviewers. ⬇	Secretariat	1 working day
5	Remind the IRB Members, Independent Consultants/Expert Reviewers, and the Principal Investigators regarding the schedule of the IRB Meeting.	Secretariat	1 working day

Detailed Instructions

2.12.8.4 Secretariat contacts the IT to prepare a schedule of the IRB Full Board/SPARES/Special Meeting.

2.12.8.5 Secretariat prepares the Agenda of the Meeting (Form 4.1) for the month.

2.12.8.6 Secretariat prepares the Minutes of the Meeting for the month.

2.12.8.7 Secretariat uploads, prepares, and sends the files that will be distributed to the reviewers.

2.12.8.8 Secretariat reminds the IRB Members, Independent Consultants/Expert Reviewers, and Principal Investigators regarding the schedule of the IRB Meeting.

2.12.9 Online Review Meeting (during the meeting)

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Quorum is monitored and ensured during the meeting.	Secretariat	1 working day
2	Meeting is initiated as soon as there is a quorum.	IRB Chair	1 working day
3	Agenda and Live Minutes is taken and shared on the screen	Secretariat	1 working day
4	Expert Reviewers and Principal Investigators wait for their queue until the secretariat admits them in the zoom room.	Secretariat	1 working day
5	Review and deliberation of the designated protocol for evaluation	IRB Reviewers	1 working day
6	Secretariat reports the other matters to the board.	Secretariat	1 working day
7	Adjournment of the meeting.	IRB Chair	1 working day

Detailed Instructions:

2.12.9.1 Secretariat makes sure that there is a quorum during the meeting.

2.12.9.2 IRB Chair initiates the meeting if quorum is met.

2.12.9.3 Secretariat shares on the screen the meeting agenda and the live minutes of the Meeting.

2.12.9.4 During the meeting, the Secretariat reminds the Expert Reviewers/Independent Consultants and the Principal Investigators to stand-by and wait for their queue until they are admitted in the zoom room.

2.12.9.5 IRB Reviewers reviews/deliberates the designated protocol for review

2.12.9.6 Secretariat reports other matters to the Board.

2.12.9.7 IRB chair adjourns the meeting.

2.12.10 Online Review Meeting (after the meeting)

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Collection of accomplished assessment forms from the reviewers. ⬇	Secretariat	1 working day
2	Collection of meeting recording from IT ⬇	Secretariat	1 working day
3	Polishing of Minutes of the Meeting ⬇	Secretariat	1 working day
4	Review, correction and approval of Minutes of the Meeting ⬇	Member-Secretary IRB Chair	1 working day 1 working day
5	Filing of Minutes of the Meeting, Agenda of the Meeting, and Accomplished evaluation forms. ⬇	Secretariat	1 working day
6	Distribution of Notification of IRB Decision to the principal investigators	Secretariat	1 working day

Detailed Instructions:

2.12.10.1 Checks completeness of accomplished evaluation forms and stores meeting materials in the cloud before deleting used files in the computer/laptop.

2.12.10.2 Secretariat collects the ZOOM cloud recording of the meeting from IT.

2.12.10.3 Secretariat completes the minutes of the meeting to be sent to the Member-Secretary for review.
Chair

2.12.10.4 IRB Chair edits the minutes of the meeting and approves it.

2.12.10.5 Secretariat archives the approved minutes of the meeting, agenda of the meeting, and accomplished evaluation forms of the reviewers.

2.12.10.6 Secretariat distributes the Notification of IRB Decision (Initial proposal, SAEs, Post approval monitoring) to the designated principal investigators.

Guidelines:

1. This policy adheres to the PHREB Resolution on the Review of Research Proposals on COVID-19. The MMC IRB is given authorization "to suspend application of pertinent provisions of their Standard Operating Procedures (SOPs) to the extent necessary to conduct online meetings to review research protocols and for other purposes."
   A. The minutes of the meeting are documented to ensure adequate recording of the review, deviation and other proceedings conducted by the board.
   B. "Due consideration must be given to the risks to privacy and confidentiality arising from the conduct of online meetings and the electronic transmission of documents";
   C. The MMC IRB "promptly reports to PHREB when such meetings are conducted and what challenges are encountered";
   D. The MMC IRB "considers immediate amendments to their SOPs to address the issues that are now being encountered because of the national health emergency and in anticipation of similar future contingencies."

2. In light of the current pandemic and restrictions with human movements, the management of submissions must all be done through electronic means and the following guidelines must be observed:
   - Only the Secretariat staff has access to the online storage platform, Microsoft OneDrive that is found inside the MMC Intranet.
   - All communications shall be recorded accurately and appropriately in the electronic log book and electronic masterlist database. Protocol-related communications are separated from administrative communications. Incoming communications shall be acted upon promptly.
   - Electronic submissions must be screened by the Secretariat Staff in the official MMC-IRB email from Monday-Friday, 08:00 AM- 5:00PM using only the official desktop/laptop computers of MMC-IRB.

- The Secretariat staff should send an acknowledgement receipt to the sender of the submission with the following details:
  - completeness of submission or lacking requirements and;
  - designated IRB code.
- Completed submissions are entered into the electronic logbook by the Secretariat with details of the following:
  - designated MMC-IRB code;
  - name of proponent;
  - type of submission;
  - date of submission and;
  - name of receiver
- Electronic folders shall be created by the Secretariat only inside the official Internet-based storage platform (MMC-IRB OneDrive) to contain all documents in the submission.
  - The electronic folder shall be labeled with the designated MMC-IRB protocol code.
  - Secretariat Staff, Member-Secretary, Chair and IRB Members must only communicate matters involving protocol submissions via official email addresses on record.

3. Face-to-face meetings shall be replaced with virtual meetings:
   - Virtual meetings are conducted through ZOOM, using the online meeting room hosted by the IT Team. Meetings shall be presided by the Chair or designated substitute.
   - Only the members of the MMC-IRB, Secretariat Staff and the IT Host are allowed to attend the meeting unless otherwise specified. The principal investigator or designated representatives and Independent Consultants, are asked to be present for a particular portion of the meeting when specific protocol is reviewed.
   - The meeting must be recorded by the IT Host and must be turned over to the IRB Secretariat within three (3) working days after the meeting. Recording will be sent only to the Member-Secretary/Secretariat. After 3 business days, IT Host will permanently delete the recording in their cloud.
   - IRB members and Secretariat Staff must secure good internet connection and clear audio during the meeting.

- IRB members must ensure that their backgrounds are free of unnecessary noise and shall ensure that their microphones are placed on mute when not delegated to share their comments. The Member-Secretary may also put the microphones on mute of other members when not in use.
  Meetings shall proceed only when quorum is declared, and shall be guided by the approved agenda.
- The presence of a conflict of interest among the members shall be disclosed prior to the discussion of each protocol for review.
- Chair may give a 5 to 10-minute break to maintain the integrity of quorum. The members are encouraged to refrain from leaving at any time during a review to maintain the quorum.
- Meeting may be suspended or terminated early once quorum is lost.
- Discussion during the meeting are organized into 2 parts:
  - Technical and Ethical Issues and;
  - Informed Consent Form
- Decision shall be done through voting. IRB members can vote by using the "raise hand" option in ZOOM.
- Primary reviewers who are not able to attend the meeting should submit the protocol and the completed assessment forms with the comments, recommendations and decision via email to the Secretariat before the meeting starts. The submitted comments, recommendations and decision are flashed on the screen during the online meeting. The Chair or member-secretary may speak in behalf of the absent reviewer.
- The decision letters shall be electronically signed by the Chair.
- Approved documents such as Informed Consent Forms and recruitment materials shall bear the electronic stamp of IRB approval and signature of the Chair.

Responsibility:

A. Chair

It is the utmost responsibility of the Chair to lead the discussion of the Board and to maintain the integrity through compliance with important guidelines in the conduct of the ethical review of the researches.

For protocol with Clinical Trial Agreements for signature of the Medical Director, the chair endorses to the Medical Director the protocols ethically cleared and approved

by the MMC IRB. It is also the responsibility of the Chair to approve the recommendations of the Member-Secretary and delegate important tasks and responsibilities to certain IRB members and staff, as deemed necessary.

B. Member Secretary

Member-Secretary is tasked to provide oversight of the Secretariat Staff to ensure that IRB operations are well-maintained. Member-Secretary serves as the Co-Host during virtual meetings and reports vital findings with regards to IRB office operations to the Chair. It is also the responsibility of the Member-Secretary to delegate tasks to the Secretariat Staff, as deemed necessary.

C. IRB Members

It is the responsibility of the members assigned as primary reviewers to thoroughly review the study protocols, give their decision, observation and comments and put all of this in the Study Assessment Forms **(Form 2.7A, 2.7B and 2.8/SJREB Form 2 and Form 3)** before returning the reviewed protocol and assessment form to the Secretariat on or before the due date via electronic means. Reviewers are present during the meeting for final deliberation and discussion.

It is the responsibility of IRB members to immediately communicate any difficulties faced in the conduct of the online reviews.

D. Secretariat Staff

It is the responsibility of the Secretariat to manage the electronic document submission, send protocol documents to the primary reviewers, refer the protocol to full board meeting for discussion and decision, communicate the review results to the Principal Investigator, keep copies of the documents in the protocol files and update the protocol entry in the IRB database and ensure privacy and confidentiality of data.

Secretariat is responsible for receiving, verifying and managing the contents of the electronic version of the submitted protocol package. In addition, the Secretariat should create a specific protocol file, make copies of the file and then distribute the copies to the Makati Medical Center IRB reviewers, together with a cover letter where the due date for returning the reviewed protocol is indicated as well as the schedule of meeting when the protocol will be discussed.

Secretariat must also coordinate with the Member-Secretary to address certain issues and in managing difficulties encountered by the reviewers during the conduct of ethical review.

MMC IRB SOP Version 8
Document History (Chapter 2)

Author	Chapter	Version	Date	Summary of Changes
Darwin A. Dasig, M.D.	2	6	November 17, 2020	• Added Section 2.12 Submission, Review and Approval of Research Protocol and Post Approval Documents during Pandemic Emergency • **Section 2.3.4.2** Added Indemnity and Insurance in the evaluation tool. • **Section 2.1.4.1 and 2.5.4.7** Revised the turnaround time to 4 weeks
Hazel Docuyanan	2	7	April 01, 2021	• Included timelines in the process flow • Identified working days as the standard timeframe instead of calendar days • Included more details – who, what, when and how in detailed instructions • Clarified the requirement of payment of review fee • Included exempted in the review type upon screening of the protocol

Hazel Faye R. Docuyanan, RPh, MS	2	8	June 09, 2021	• Revised item D in Section 2.7.4.4 p.35, to state "for Full Board Discussion" instead of "Disapproved" • The forms are revised to indicate only the contact numbers and email address of the IRB Secretariat Staff to ensure that in case of resignation or changes, there will be no need to change the whole form.

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

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.

Document Title	No. of Copies
☐ Protocol Summary Sheet (2.5)*	1
☐ Protocol Evaluation Form (2.7A, 2.7B)*	1
☐ Informed Consent Evaluation Form (Form 2.8)*	1
☐ Letter of Intent*	1
☐ Endorsement Letter/Technical Approval (for in-house residents and fellows only)*	1
☐ Protocol*	1
☐ Ethical Considerations and Statement of Agreement *	1
☐ **Informed Consent Form**	
English**	1
Filipino**	1
Local Dialect**	1
☐ **Assent Forms**	1
English**	
Filipino**	
☐ Case Report Forms (CRF) or Data*	1
☐ Collection Form*	1

Document Title	No. of Copies
☐ Recruitment Materials**	1
☐ Gantt Chart*	1
☐ Flow Chart*	1
☐ Study Budget*	1
☐ FDA Approval**	1
☐ Investigator's Brochure**	1
☐ Curriculum Vitae of Principal Investigator*	1
☐ GCP Certificate of Principal Investigator*	1
☐ Curriculum Vitae of Co-investigator/s*	1
☐ GCP Certificate of Co-investigator/s*	1
☐ Protocol Review Fee Receipt	1

Legend:

* mandatory ** if applicable

All requirements must be submitted online to the official IRB email: irbmmc.admin@makatimed.net.ph for screening. After receiving an e-mail notification that your submission is "complete", submit one (1) hard copy to the IRB Office located at the 7th Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City. You may contact the IRB Secretariat Staff through the following:

1. Telephone: 8888-8999 Loc. 3973, 3972 and 7166
2. Email: irbmmc.admin@makatimed.net.ph

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 – 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)	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.		

Submitted documents in letter sized paper (please specify):

Click here to enter text.

All requirements must be submitted online to the official IRB email: irbmmc.admin@makatimed.net.ph for screening. After receiving an e-mail notification that your submission is "complete", submit one (1) hard copy to the IRB Office located at the 7th Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City. You may contact the IRB Secretariat Staff through the following:

1. Telephone: 8888-8999 Loc. 3973, 3972 and 7166
2. Email: irbmmc.admin@makatimed.net.ph

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.

All requirements must be submitted online to the official IRB email: irbmmc.admin@makatimed.net.ph for screening.
After receiving an e-mail notification that your submission is "complete", submit one (1) hard copy to the IRB Office located at the 7th Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City. You may contact the IRB Secretariat Staff through the following:

1. Telephone: 8888-8999 Loc. 3973, 3972 and 7166
2. Email: irbmmc.admin@makatimed.net.ph

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)

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

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

Put a check mark (✓)	NUMBER OF COPIES	DOCUMENT SUBMITTED
	1	Accomplished forms: -Application Form (Form 2.1)
	1	-Protocol Summary Sheet (Form 2.5)
	1	-Protocol Information (Form 2.7A)
	1	-Protocol Evaluation (Form 2.7B)
	1	-Informed Consent Evaluation Form (Form 2.8)
	1	Letter of intent with itemized documents submitted.
	1	Accomplished Research Protocol Evaluation Forms (REFORM) signed by the Department Chair. (for In-house Residents, Fellows and Interns only)
	1	Detailed protocols and other protocol-related documents
	1	Gantt Chart of the Protocol
	1	Curriculum vitae and Good Clinical Practice Certificate (updated every 3 years) of the Principal Investigator and Co-investigator(s).
	1	PowerPoint Presentation of the brief summary of the research
If applicable, submit the following:		
	1	Informed Consent Forms (English and Tagalog and/or other applicable dialect)
	1	Assent Form
	1	Case Report Forms or Data Collection Forms
	1	Diary Cards and other materials related to the study (e.g., recruitment materials, etc.)
	1	Study Budget
	1	Certification of FDA approval to conduct the trial in the Philippines (*parallel review by MMC IRB while awaiting FDA approval is allowed)
	1	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 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 Contact Number	Click here to enter text.	**Date of Approval** (MMM/DD/YYYY)	Click here to enter text.
Protocol Title	Click here to enter text.		

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
☐	Institutional fee of Php120,000.00 (net of withholding tax). This will only cover the processing fee and legal review fee. **Note: 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
☐	Soft copy of the Clinical Trial Agreement (CTA), preferably in Microsoft Word Format **Note: Submit to the official IRB email: irbmmc.admin@makatimed.net.ph.*
☐	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.*

The soft copy of the CTA must be submitted online to the official IRB email: irbmmc.admin@makatimed.net.ph.
Submit the six (6) original hard copies to the IRB Office located at the 7TH Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City. You may contact the IRB Secretariat Staff through the following:

1. Telephone: 8888-8999 Loc. 3973, 3972 and 7166
2. Email: irbmmc.admin@makatimed.net.ph

Submitted by:

Signature above Printed Name

Date (MMM/DD/YYYY)

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

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	Click here to enter text	**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**	Click here to enter text.

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)
☐ 1	Protocol Evaluation Form 2.7A
☐ 1	Protocol Evaluation Form for Resubmission 2.7C (for resubmission)
☐ 1	Protocol Amendment Review Form 3.2 (for amendments)
☐ 1	Letter of intent including the list of documents submitted
☐ 1	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)
☐ 1	Resubmitted or amended documents (including a copy of the IRB queries for resubmissions)

No. of Copies	DOCUMENT SUBMITTED
	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

All requirements must be submitted online to the official IRB email: irbmmc.admin@makatimed.net.ph for screening.
After receiving an e-mail notification that your submission is "complete", submit one (1) hard copy to the IRB Office located at the 7th Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City. You may contact the IRB Secretariat Staff through the following:

1. Telephone: 8888-8999 Loc. 3973, 3972 and 7166
2. Email: irbmmc.admin@makatimed.net.ph

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**	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.		
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.		

All requirements must be submitted online to the official IRB email: irbmmc.admin@makatimed.net.ph for screening.
After receiving an e-mail notification that your submission is "complete", submit one (1) hard copy to the IRB Office located at the 7th Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City. You may contact the IRB Secretariat Staff through the following:

1. Telephone: 8888-8999 Loc. 3973, 3972 and 7166
2. Email: irbmmc.admin@makatimed.net.ph

Protocol Title		**IRB Protocol Number**	

Principal Investigator		**GCP**	☐
Co-Investigator/s		**GCP**	☐
		GCP	☐
		GCP	☐

NOTE: *KINDLY MAKE SURE THE VALIDITY OF THE GCP IS WITHIN THE STUDY DURATION.*

Type of Research	☐ Clinical Trial, Phase:	☐ Epidemiological
	☐ Basic Science	☐ Social Science
	☐ Behavioral	☐ Other:

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

Type of Submission	☐ Initial Submission (New Protocol)	☐ Progress Report
	☐ Resubmission	☐ Other:
	☐ Amendment	

Type of Review of Previous Submission	☐ Full Board	☐ Expedited (SPARES)
	☐ Full Board (SJREB)	☐ Expedited (SJREB)
	☐ Exempted	☒ NA

Primary Reviewer's Name	GCP	To review
	☐	☐ Main Protocol ☐ Informed Consent
	☐	☐ Main Protocol ☐ Informed Consent
	☐	☐ Main Protocol ☐ Informed Consent

NOTE: *REVIEWERS ARE EXPECTED TO THEIR SUBMIT THEIR ACCOMPLISHED ASSESSMENT FORM WITHIN THREE (3) DAYS UPON ENDORSEMENT OF THE IRB SECRETARIAT*

TO THE MEMBER-SECRETARY: *KINDLY ACCOMPLISH THE CHECKLIST BELOW:*

		INITIAL SUBMISSION
	ISER	**EXPEDITED REVIEW (SPARES)**
☐	**1**	1. Protocols of a non-confidential nature (not of a private character, e.g. relate to sexual preference etc., or not about a sensitive issue that may cause social stigma), not likely to harm the status or interests of the study participants and not likely to offend the sensibilities nor cause psychological stress of the people involved.
☐	**2**	Protocols not involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to participate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent).
☐	**3**	Protocols that involve collection of anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).
☐	**4**	Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis
	ISFB	**FULL BOARD REVIEW**
☐	**1**	Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3)
☐	**2**	Phase 4 intervention research involving drugs, biologics or device
☐	**3**	Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc., or about sensitive issues that may cause social stigma) that may cause psychological, legal, economic and other social harm
☐	**4**	Protocols involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to participate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent) that require additional protection from the IRB during review
☐	**5**	Protocols that involve collection of identifiable biological specimens for research

		AMENDMENT (AMER)**/RESUBMISSION** (RSER)
		EXPEDITED REVIEW (SPARES)
		protocol amendments that have minor modifications and no significant risk to study participants, such as:
☐	**1**	Administrative revisions, such as correction of typing errors
☐	**2**	Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
☐	**3**	The research activity includes only minor changes from previously approved protocol.
☐	**4**	Minor protocol amendments that do not change the risk/ benefit assessment
		AMENDMENT (AMFB)**/RESUBMISSION** (RSFB)**/PROGRESS REPORT** (PRFB)
		FULL BOARD REVIEW
☐	**1**	Major revisions of the protocol and informed consent after initial review
☐	**2**	Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/ exclusion criteria, safety issues, etc.)
☐	**3**	Major amendments that change the risk/ benefit ratio
☐	**4**	Renewal of protocol approval to continue study

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

	EX	**EXEMPTION**
☐	**1**	Study that does not involve human participants nor identifiable tissue, biological samples and data
☐	**2**	Study design is meta-analysis and/or systemic with identifiable data
☐	**3**	Case Reports
☐	**4**	Study with less than minimal risk or harm
☐	**5**	Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests

Type of Review	☐ Full Board ☐ Exempted ☐ NA	☐ Expedited (SPARES) ☐ Expedited (SJREB)
Justification of Type of Review		

Recommended by:	**Approved by:**
<Member-Secretary> Signature and Date over Printed Name	<Chair> Signature and Data over Printed Name

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

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**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s) (if any)**	Click here to enter text.
Principal Investigator's Contact Number	Click here to enter text.	**Principal Signature**	Click here to enter text.
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: _ _ Click here to enter text.		
	☐ 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	☐ Yes	☐ Not Applicable
	☐ No	

between MMC the external organization?	

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

TO THE PRINCIPAL INVESTIGATOR: *FOR THE APPLICATION FOR EXEMPTION FROM REVIEW, INDICATE WITH A (✓) CHECK MARK THE APPROPRIATE TICK BOX APPLICABLE FOR YOUR SUBMISSION.*

Criteria for Exemption	☐ Does not involve human participants nor identifiable tissue, biological samples and data
	☐ Study design is meta-analysis and/or systemic with identifiable data
	☐ Case Reports
	☐ Study with less than minimal risk or harm
	☐ Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests

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. Significance of the Study/Social Value	Click here to enter text.		
4. Literature Review/ Investigator's Brochure	Click here to enter text.		
5. Research Design	Click here to enter text.		

6. Sampling Design, Sample size or Number of subjects to be enrolled	Click here to enter text.		
7. Statistical/ Data Analysis	Click here to enter text.		
8. Methodology	Click here to enter text.		
9. Control Arm (Placebo, if any)	Click here to enter text.		
10. Standard Therapy	Click here to enter text.		
11. Inclusion Criteria	Click here to enter text.		
12. Exclusion Criteria	Click here to enter text.		
13. Withdrawal or Discontinuation Criteria	Click here to enter text.		
14. Specimen Handling	Click here to enter text.		
15. Principal Investigator's Qualifications	Click here to enter text.		
16. Duration	Click here to enter text.		
17. Conflict of Interest a. Involvement of the Investigator in any other	Click here to enter text.		

similar or competing trial *(*For COVID-19 vaccine protocols only)*			
18. Privacy and Confidentiality	Click here to enter text.		

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

	constitution of the Data Safety Monitoring Board (DSMC)/ Food and Drug Administration (FDA) Approval			
29.	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. | Click here to enter text.

Signature above Printed Name | **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	Click here to enter text.	**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>		

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:

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 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)	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.		

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

☐ 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)

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 understandable?
   ☐ Clear ☐ Unclear
   Comment:

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 provision for compensation?

☐ Appropriate ☐ Inappropriate

Comment:

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

☐ Appropriate ☐ Inappropriate

Comment:

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

☐ Yes ☐ No

Comment:

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

☐ Yes ☐ No

Comment:

19. 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:

20. 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:

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

☐ 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 DATE OF DELIBERATION 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)

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)	Click here to enter text.	**IRB Protocol Number**	Click here to enter text.
Sponsor	Click here to enter text.	**Sponsor's Protocol Number**	Click here to enter text.
Principal Investigator	Click here to enter text.	**Co-investigator(s) (if any)**	Click here to enter text.
Protocol Title	Click here to enter text.		
Protocol Version Number	Click here to enter text.	**Version Date** (MMM/DD/YYYY)	Click here to enter text.
Other Documents	Click here to enter text.		

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

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

Decision Points in the Protocol	☐ Approved ☐ Minor revisions required ☐ Major revisions required	☐ Disapproved ☐ Pending Decision

Decision Points for the Informed Consent Form	☐ **Approved** ☐ **Minor Modifications** ☐ **Major Modifications**	☐ **Disapproved** ☐ **Pending Decision**
Reason for decision	Click here to enter text.	
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)
Click here to enter text.	Click here to enter text.	Click here to enter text.

All requirements must be submitted online to the official IRB email: irbmmc.admin@makatimed.net.ph for screening. After receiving an e-mail notification that your submission is "complete", submit one (1) hard copy to the IRB Office located at the 7th Floor, Keyland Center (Makati Medical Center Tower 3), 143 Dela Rosa cor. Adelantado Streets, Legaspi Village, Makati City. You may contact the IRB Secretariat Staff through the following:

1. Telephone: 8888-8999 Loc. 3973, 3972 and 7166
2. Email: irbmmc.admin@makatimed.net.ph

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

GENERAL INFORMATION OF STUDY DEVICE	
Name of Study Device	Click here to enter text.
Sponsor/ Manufacturer	Click here to enter text.
Indication for Use	Click here to enter text.

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.	Click here to enter text.	Click here to enter text.
2. Proposed investigational plan (Use of the device in the study)	Click here to enter text.	Click here to enter text.
3. Reports of prior investigations conducted with the device	Click here to enter text.	Click here to enter text.
4. FDA Approval, IDE Number	Click here to enter text.	Click here to enter text.
5. Risk assessment determination for new investigational device (Significant Risk or Non Significant Risk) and its rationale	Click here to enter text.	Click here to enter text.

6. Choice of comparator and justification (if applicable)	Click here to enter text.	Click here to enter text.
7. Summary of the necessary training and the experience needed to use the investigational device	Click here to enter text.	Click here to enter text.
8. Device control, access and accountability	Click here to enter text.	Click here to enter text.
9. List of additional procedures (example: surgery), medical device or medication to be used as part of the investigational study	Click here to enter text.	Click here to enter text.
10. Risk-benefit assessment	Click here to enter text.	Click here to enter text.
11. Safety and effectiveness/ performance assessments	Click here to enter text.	Click here to enter text.
12. Prohibition against promotion or commercialization of, and certain other practices relative to, investigational devices	Click here to enter text.	Click here to enter text.
13. References	Click here to enter text.	Click here to enter text.

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**	Click here to enter text.
Intended as an implant and presents a potential serious risk to the health, safety or welfare of a subject.			Click here to enter text.
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.			Click here to enter text.
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.			Click here to enter text.

Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject;			Click here to enter text.

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.*			Click here to enter text.
IDE Exempt Study Device			Click here to enter text.

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

☐ Minor Modification:

Summary of Revisions:

☐ Major Modification:

Summary of Revisions:

☐ Disapproval

Reason:

☐ Pending Decision

Reason:

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