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<dd/mm/yyyy>

**<TITLE, NAME, SURNAME OF PI>**

Principal Investigator

<Institution/Affiliation>

<Address>

|  |  |
| --- | --- |
| **Re:** | **<MMMC-RERC Code>** |
| **<Study Protocol Title>** |

Dear **<TITLE OF PI><SURNAME>**:

We wish to inform you that your study protocol has been reviewed on <date of meeting> and is hereby granted approval for implementation by the **Mary Mediatrix Medical Center- Research Ethics Review Committee.** Your study has been assigned study protocol code **<MMMC-RERC code>,** which should be used for all communications to the MMMC-RERC related to this study. This ethical clearance is valid until <**expiration date>.**

As a result of the <type of review> review, the following documents have been approved for use in the study.

1. Study Protocol <version #><date of document>
2. Study Protocol file 1 <version #><date of document>
3. Study Protocol file 2 <version #><date of document>

In addition to the abovementioned documents, the following technical document/s was/were included in the review on which this approval was based:

1. Study Protocol file 3 <version #><date of document>
2. Study Protocol file 4 <version #><date of document>

While the study is in progress, we request you to submit to us the following documents:

1. Progress report using the attached MMMC-RERC F-3-B: *every (no. months/year).* Included in the report are the following: (*NOTE: In view of active ethical clearance, this report is mandatory even if the study has not started or is still awaiting release of funds*.)
   1. Date covered by the report
   2. Protocol summary and status report on the progress of the research
   3. Status of registration of study in Philippine Health Research Registry (http://registry.healthresearch.ph)
   4. Number of participants accrued
   5. Withdrawal or termination of participants
   6. Complaints on the research since the last MMMC-RERC review
   7. Summary of relevant recent research literature, interim findings and amendments since the last MMMC-RERC review
   8. Any relevant multi-center research reports
   9. Any relevant information especially about risks associated with the research
   10. A copy of the informed consent document

2. Any amendment/s in the protocol, especially those that may adversely affect the safety

of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using the attached: **MMMC-RERC F-3-D: Study Protocol / Informed Consent Amendment Submission Form.**

3. Revisions in the informed consent form using the attached **MMMC-RERC F-3-D:**

**Study Protocol /Informed Consent Amendment Submission Form.**

4. Reports of adverse events including from other study sites (national, international)

using the attached **MMMC-RERC F-3-G/H/I: Serious Adverse Events Report Form**, with timelines for submission guided by the attached GL 01 Version 1.1: Guideline on Reporting Serious Adverse Events.

5. Notice of early termination of the study and reasons for such using

**MMMC-RERC F-3-K.**

6. Any event which may have ethical significance.

7. Any information which is needed by the MMMC-RERC to do ongoing review

8. Notice of time of completion of the study using **MMMC-RERC F-3-C**: Final Report

Form.

9. Application for renewal of ethical clearance 90 days before the expiration date of this

approval through submission of **MMMC-RERC F-3-E:** Continuing Review Application Form, if the study will continue beyond expiration date of ethical clearance.

Please note that forms may be downloaded from the MMMC-RERC website:

Thank you.

Very truly yours,

**<NAME OF REVIEW CHAIR>**

Chair, MMMC-RERC

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**MMMC-RERC Code:**

**Protocol Number:**

**Protocol Title:**

**Principal Investigator:**

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| Research Ethics Review Committee | | | |
| **Name** | **Position** | **Qualification/Profession** | **Affiliation to MMMC** |
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Comments:

This certifies that the Research Ethics Review Committee of Mary Mediatrix Medical Center, the committee that reviewed and approved the aforementioned protocol, is **ICH-GCP Compliant.**

Signed by:

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**<NAME OF REVIEW CHAIR>**

Chair, Research Ethics Review Committee

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Date