|  | **Far Eastern University – Dr. Nicanor Reyes Medical Foundation**  **INSTITUTIONAL ETHICS REVIEW COMMITTEE**  Rm 218, 2nd Floor, Institute of Medicine  Regalado Avenue near Dahlia Street, West Fairview, Quezon City 1118  Telefax: +63 (02) 8-9838338 loc 1236; Email: ierc@feu-nrmf.edu.ph |
| --- | --- |

<mm/dd/yyyy>

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

Principal Investigator

<Institution/Affiliation>

<Address>

| **Re:** | **<FEU-NRMF IERC Code>** |
| --- | --- |
| **<Study Protocol Title>** |

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

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the **FEU-NRMF Institutional Ethics Review Board (FEU-NRMF IERC)**. Your study has been assigned study protocol code <FEU-NRMF IERC code>, which should be used for all communication to the FEU-NRMF IERC related to this study. This ethical clearance is valid from **<date of effectivity>** until <**expiration date>.**

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 above mentioned 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. FEU-NRMF IERC FORM 3(L) 2022: Progress Report Form every <12 months (for low and minimal risk studies)/6 months (for moderate risk studies)/3 months (for high-risk studies)>.
2. FEU-NRMF IERC FORM 3(B) 2022: Continuing Review Application Form every twelve months <date> from date of approval which includes 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. Number of participants accrued
   4. Withdrawal or termination of participants
   5. Complaints on the research since the last FEU-NRMF IERC review
   6. Summary of relevant recent research literature, interim findings and amendments since the last FEU-NRMF IERC review
   7. Any relevant multi-center research reports
   8. Any relevant information especially about risks associated with the research
   9. A copy of the informed consent document
3. Any changes 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 FEU-NRMF IERC FORM 3(A) 2022: Study Protocol Amendment Submission Form.
4. Revisions in the informed consent form using the attached FEU-NRMF IERC FORM 3(A) 2022: Study Protocol Amendment Submission Form.
5. Reports of adverse events including from other study sites (national, international) using the attached FEU-NRMF IERC FORM 3(G) 2022: Adverse Events Report.
6. Notice of early termination of the study and reasons for such using FEU-NRMF IERC FORM 3(E) 2022.
7. Any event which may have ethical significance.
8. Any information which is needed by the FEU-NRMF IERC to do ongoing review
9. Notice of time of completion of the study using FEU-NRMF IERC FORM 3(C) 2022: Final Report Form not later than sixty (60) days after the end of the study.
10. Application for renewal of ethical clearance **thirty (30)** days before the expiration date of this approval through submission of FEU-NRMF IERC FORM 3(B) 2022: Continuing Review Application Form

In order to protect study participants, study sites may be selected for site visits based on:

1. The nature of the study being conducted (i.e. high risk studies)
2. Frequent non-submission or failure to submit continuing review requirements
3. Reports of major protocol noncompliance
4. Significant number of serious adverse events
5. Reports of complaints from study participants
6. Recommendation of the Committee

Thank you.

Very truly yours,

**<NAME OF FEU NRMF IERC CHAIR>**

Chair, FEU-NRMF IERC