**<<DATETODAY>>**

This is to certify that the following protocol with related documents have been reviewed and is hereby granted **APPROVAL** by the St. Paul University Philippines Research Ethics Committee (SPUP REC) for implementation.

|  |  |
| --- | --- |
| SPUP REC Code | **<<REC\_CODE>>** |

|  |  |
| --- | --- |
| Protocol Title | <<PROTOCOL\_TITLE>> |
| Principal Investigator | <<PRINCIPAL\_INVESTIGATOR>> |
| Adviser | <<ADVISER>> |

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol Version No. | 02 | Version Date | **<<DATE\_TODAY>>** |
| ICF No. | 02 | Version Date | **<<DATE\_TODAY>>** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Duration of Approval | **<<DATE\_TODAY>>-**  **<<DATE\_PLUS>>** | | Frequency of Progress Report | | **EVERY THREE (3) MONTHS** |
| Type of Review |  | Full Board |  | Expedited | |
| Date of initial review | **<<LESSDATE>>** | | | | |

**Primary investigator’s responsibilities after Approval:**

1. Submit protocol amendment documents using **Protocol Amendment Application Form** for SPUP REC approval before implementing them.
2. Submit revisions in the Informed Consent Form using **Protocol Amendment Application Form**
3. Submit Reportable Negative Events within three (3) days from occurrence of event using **Reportable Negative Events Report Form**
4. Submit progress report using **Progress Report Form** every **THREE (3)** months or as deemed necessary and depending on the duration of the study.
5. Submit a continuing review application using **Continuing Review Application** form on or before the expiration of SPUP approval.
6. Submit final report using **Final Report Form** after completion of protocol procedures.
7. Report protocol non-compliance/deviation/ violation using **Study Protocol Noncompliance/Deviation Report Form**.
8. Notice of early termination of the study and reasons for such using **Early Study Termination Form.**
9. Comply with all relevant international and national guidelines and regulations.
10. Abide by the principles of good clinical practice and ethical research.

**Rita B. Daliwag, MST, LPT**

Chairperson, Research Ethics Committee

Date: **<<DATETODAY>>**