<Date>

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.

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| --- | --- |
| SPUP REC Code |  |

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| --- | --- |
| Protocol Title |  |
| Principal Investigator |  |
| Adviser |  |

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| --- | --- | --- | --- |
| Protocol Version No. |  | Version Date |  |
| ICF No. |  | Version Date |  |

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| Duration of Approval |  | | Frequency of Progress Report | |  |
| Type of Review |  | Full Board |  | Expedited | |
| Date of initial review |  | | | | |

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

1. Submit protocol amendment documents using Form10A. Protocol Amendment Application Form for SPUP REC approval before implementing them.
2. Submit revisions in the Informed Consent Form using Form10A. Protocol Amendment Application Form
3. Submit Reportable Negative Events within three (3) days from occurrence of event using Form 12A. Reportable Negative Events Report Form
4. Submit progress report using Form 9A. Progress Report Form every <#> months or as deemed necessary and depending on the duration of the study.
5. Submit a continuing review application using Form 13A. Continuing Review Application form on or before the expiration of SPUP approval.
6. Submit final report using Form 14A. Final Report Form after completion of protocol procedures.
7. Report protocol non-compliance/deviation/ violation using Form 11A. Study Protocol Noncompliance/Deviation Report Form.
8. Notice of early termination of the study and reasons for such using Form 15A. 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.

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Chairperson, Research Ethics Committee

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

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| Signature over Printed Name |
| Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |