Form 27.1 Approval Letter

**Eastern Visayas Health Research and Development Consortium - Ethics Review Committee**

***APPROVAL LETTER***

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

This is to certify that the following protocol and related documents have been granted approval by the **Eastern Visayas Health Research and Development Consortium - Ethics Review Committee** for implementation.

|  |  |  |  |
| --- | --- | --- | --- |
| ERC Protocol No. |  | Sponsor Protocol No. |  |
|  |  |  |  |
| Principal Investigator/s |  | Sponsor |  |
|  |  |  |  |
| Title |  |  |  |
|  |  |  |  |
| Protocol Version No. |  | Version Date |  |
|  |  |  |  |
| ICF Version No. |  | Version No. |  |
|  |  |  |  |
| Other Documents |  | | |
|  |  |  |  |
| Type of Review | ☐ Expedited  ☐ Full review  Meeting date: | Duration of Approval from (date) to | Frequency of Continuing Review |

Investigator Responsibilities after Approval:

* Submit document amendments for ERC approval before implementing them. No amendment in the protocol or ICF shall be implemented without the ERC approval.
* Submit SAE and SUSAR reports to the ERC within 7 days
* Submit Reportable Negative Events to the ERC within 3 days
* Submit progress report every \_\_\_\_\_\_\_
* Submit the final report no later than 1 month after the end of the study
* Apply for continuing review no less than 60 calendar days before the expiry of ethical clearance
* Report protocol deviation/ violation within 7 days
* Comply with all relevant international and national guidelines and regulations
* PI to accommodate possible SITE VISIT
* Abide by the principles of good clinical practice and ethical research.

Very truly yours**,**

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Chair, Ethics Review Committee

Eastern Visayas Health Research and Development Consortium