Form 8.2 Certificate of Exemption from Ethics Review

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

***CERTIFICATE OF EXEMPTION FROM ETHICS REVIEW***

This is to certify that the following protocol and related documents have been reviewed and granted exemption from review by the Eastern Visayas Health Research and Development Consortium – Ethics Review Committee for implementation.

**Note:**

It is the responsibility of the Principal Investigator to report any changes that may affect the exemption granted and submit a final report at the end of the study.

| ERC Protocol No. |  |
| --- | --- |

| Principal Investigator/s |  | Sponsor |  |
| --- | --- | --- | --- |

| Title |  |
| --- | --- |

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

| ICF Version No. |  | Version Date |  |
| --- | --- | --- | --- |
| Other documents |  |  |  |

| ERC Chair | Name | Signature | Date |
| --- | --- | --- | --- |
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| **RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR WHILE STUDY IS IN PROGRESS:**1. Continuing compliance with the exemption criteria of the National Ethical Guidelines for Health and Health-Related Research 2017 in the duration of the study;
2. Nonetheless, such human participants in case reports/case series/non-health research are entitled to compliance of researchers with universal ethical principles of respect for persons, beneficence, and justice, as well as applicable local regulations, including the Data Privacy Act of 2012 (RA 10173). Thus, it is the responsibility of the author/investigator/s to ensure satisfactory compliance with the aforementioned principles and all applicable regulations, and to obtain informed consent from the human subjects involved, if personally identifiable information will be used in any way.
3. No substantial changes in research design, methodology and subject population from the protocol submitted for exemption. Modifications that significantly affect previous risk-benefit assessment or qualification for exemption may be submitted as a new protocol for initial review.
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Protocols that qualify for **EXEMPTION** are automatically archived and classified as **INACTIVE**, and protocol records will be made available by EVHRDC ERC for three years from date of action. Study protocols granted for exemption are exempt from further review including continuing review. EVHRDC-ERC must be provided with a copy of the FINAL report not later than one (1) month from the end of study. All further queries regarding this request may be forwarded to the undersigned through evhealthresearch2020@gmail.com or telephone number (053) 888 - 4203.