Form 13.1 Study Protocol Amendment

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

***STUDY PROTOCOL AMENDMENT***

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *A study protocol amendment is a written description of a change(s) to or formal clarification of a protocol and/or informed consent documents. Favorable opinion or approval should be obtained from the ERC that issued the ethical clearance or approval prior to the implementation of an amendment. Obtain an electronic copy of this form and encode all information required in the space provided. Multiple amendments classified under ONE type of review (expedited or full review) can be submitted in one form. Print the report in A4 size paper; then date and sign this form before submission.*

| **PROTOCOL CODE:** | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **STUDY PROTOCOL TITLE:** | | | | | | | | | | | |
| **APPROVAL DATE:** <dd/mm/yyyy> | | | | | | | | | | | |
| **PRINCIPAL INVESTIGATOR:** | | | | | | | | | | | |
| **Email:** | | | | **Telephone:** | | | | **Mobile:** | | | |
| **STUDY SITE:** <Name and address> | | | | | | | | | | | |
| **STUDY SITE ADDRESS:** | | | | | | | | | | | |
| **SPONSOR:** | | | | | | | | | | | |
| **SPONSOR CONTACT PERSON:** | | | | | | | | | | | |
| **Email:** | | | | **Telephone:** | | | | **Mobile:** | | | |
| **AMENDMENT SUBMISSION DATE:** (to be filled out by EVHRDC-ERC) <dd/mm/yyyy> | | | | | | | | | | | |
| **1. Item/procedure to be amended in the approved protocol/ICF** | | | **2. Proposed Amendment** *(indicate page # where amendment is found)* | | | **3. Justification** | | | **4. ERC Review Assessment**  *(to be filled out by the ERC)* | | |
| 1. **Protocol** | | | | | | | | | | | |
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| **B. Informed Consent Form** | | | | | | | | | | | |
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| **5. TYPE OF REVIEW**:  **5.1.** ⬜ **EXPEDITED** REVIEW FOR AMENDMENTS THAT:   * + - Do not involve changes in study populations     - Do not involve the collection of stigmatizing information     - Do not change approved use of anonymized or archived samples     - Do not involve further recruitment of participants     - Involve study protocols previously classified under expedited review     - Are administrative in nature (such as contact details of study personnel)     - Do not materially affect the risk-benefit ratio of the approved protocol or increase risks to study participants   5.2⬜ **FULL REVIEW** for any amendments not cited under EXPEDITED REVIEW | | | | | | | | | | | |
| **SIGNATURE OF PRINCIPAL INVESTIGATOR:** | | | | | | | | | | | |
| ***For EVHRDC-ERC use only*** | | | | | | | | | | | |
| Primary Reviewers | | | | Signature | | | | Date | | | |
| 1. | | | |  | | | | <dd/mm/yyyy> | | | |
| 2. | | | |  | | | | <dd/mm/yyyy> | | | |

| **RECOMMENDED ACTION: (for EVHRDC- ERC use only)**   * APPROVAL * MINOR MODIFICATION TO THE STUDY PROTOCOL , SUBJECT TO EXPEDITED REVIEW AT THE LEVEL OF THE PANEL CHAIR * MAJOR MODIFICATION TO THE STUDY PROTOCOL, SUBJECT TO FULL PANEL REVIEW * DISAPPROVAL |
| --- |
| **COMMENTS:** (*identify items for revision) Write comments of all members if full board* |
| Signature  **EVHRDC MEMBER SECRETARY** |
| Date: <dd/mm/yyyy> Name <Title, Name, Surname> |
| Signature  **EVHRDC ERC CHAIR** |
| Date: <dd/mm/yyyy> Name <Title, Name, Surname> |