Form 15.1 Study Protocol Noncompliance (Deviation or Violation)

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

***STUDY PROTOCOL NONCOMPLIANCE (DEVIATION OR VIOLATION)***

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *Obtain an electronic copy of this form and encode all information required in the space provided. Multiple deviations/violations classified under ONE type of review (expedited or full review) can be submitted in one form; then date and sign this form before submission.*

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| **PROTOCOL CODE:**  |
| **STUDY PROTOCOL TITLE:**  |
| **APPROVAL DATE:**  |
| **PRINCIPAL INVESTIGATOR:**  |
| **Email:**  | **Telephone:**  | **Mobile:**  |
| **STUDY SITE:**  |
| **STUDY SITE ADDRESS:**  |
| **SPONSOR:**  |
| **SPONSOR CONTACT PERSON:**  |
| **Email:**  | **Telephone:**  | **Mobile:**  |
| **Ethical clearance effectivity period**  |  |
| 1. **Progress Report**
 |
| Start of study |  | Expected end of study |  |
| Number of enrolled participants |  | Number of required participants |  |
| Number of participants who withdrew |  |  |  |
| 1. **Indicate each protocol deviation/violation:**
 | **Actions taken to prevent future deviation/violation** |
| 123 | 123 |
| 1. **Impact of deviation/violation on participants’ risks/harms and integrity of data**
 | **How would you address these factors?** |
|  |  |
| **DATE OF DEVIATION/VIOLATION:** <dd/mm/yyyy> |
| **REPORTED BY:**  |
| **DATE OF REPORT:** <dd/mm/yyyy> |
| **PI SIGNATURE:** |

***FOR EVHRDC ERC USE ONLY***

|  |  |
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| **PROTOCOL CODE:** |  |
| **STUDY PROTOCOL TITLE:** |  |
| **APPROVAL DATE:**  |  |
| **PRINCIPAL INVESTIGATOR:**  |  |
| **Email:**  | **Telephone/Mobile:**  |
| Study Site Name: | Study Site Address: |
| NATURE OF REPORTMINOR PROTOCOL DEVIATION - (non-systematic protocol noncompliance with minor consequences, in terms of its effect on the participant’s/subject’s rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature)MAJOR PROTOCOL DEVIATION - Persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients’ safety at risk) |
| DESCRIPTION OF REPORTED DEVIATION/VIOLATION: |
| DESCRIPTION OF INVESTIGATOR CORRECTIVE ACTION: Found by: Principal Investigator/Study Team Sponsor/Monitor EVHRDC ERC Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Reported by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Recommended Action:☐ NO FURTHER ACTION; UPHOLD ETHICAL CLEARANCE☐ SUBMIT ADDITIONAL INFORMATION: Specify what information is needed☐ RECOMMEND FURTHER ACTION: specify the required action e.g. to institute protocol amendment to correct future deviations/violations☐ SUBMIT CAPA (Corrective and Preventive Action)☐ WITHDRAW ETHICAL CLEARANCE: Indicate reason☐ SUSPEND PARTICIPANT RECRUITMENT UNTIL NON-COMPLIANCE ISSUES ARE ADDRESSED |
| PRIMARY REVIEWERS12 | Signature | Date Signed |
| Other reviewers123 |  |  |
| ERC Member-Secretary:Date: |
| ERC Chair:Date: |