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** | | |
| 1  2  3 | | | 1  2  3 | | |
| 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 REPORT  MINOR 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 REVIEWERS  1  2 | Signature | | Date Signed |
| Other reviewers  1  2  3 |  | |  |
| ERC Member-Secretary:  Date: | | | |
| ERC Chair:  Date: | | | |