Form 20.3 Site Visit Report

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

***SITE VISIT REPORT***

**INSTRUCTIONS TO THE ERC MEMBERS:** *A Site Visit is conducted as result of full board action for purposes of monitoring study protocol compliance in the study site. The visit is limited to the review of study protocol related documents and procedures that have been approved by the EVHRDC-ERC that issued the ethical clearance or approval of the study. The visit should not in any way compromise the obligation to protect the privacy and confidentiality of research-related information of study participants/subjects. The ERC Chair should ensure that the Site Visit Team is well-prepared to conduct the visit through a complete review of the study protocol folder prior to the visit. This form should reflect the consensus opinion of the Site Visit Team.*

| **EVHRDC ERC 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:** | |
| **SITE VISIT DATE:** <dd/mm/yyyy> | | | | |
| **1. Total participants expected:** | | | | |
| **2. Total participants enrolled:** | | | | |
| 1. **Are site facilities appropriate?**     1. ⬜ YES    2. ⬜ NO    3. COMMENTS: | | | | |
| 1. **Are informed consent documents updated to the version approved by the EVHRDC ERC ?**     1. ⬜ YES    2. ⬜ NO    3. COMMENTS: | | | | |
| 1. **Are there any SAE/SUSAR reports not previously reported to the EVHRDC ERC?**     1. ⬜ YES    2. ⬜ NO    3. COMMENTS | | | | |
| 1. **Are there any events of protocol noncompliance not previously reported to the EVHRDC ERC?** 2. 6.1. ⬜ YES   6.2. ⬜ NO  6.3. COMMENTS | | | | |
| 1. **Are investigation products and study documents secured adequately?**     1. ⬜ YES    2. ⬜ NO    3. COMMENTS | | | | |
| 1. **Are all other EVHRDC ERC -approved documents (e.g. advertisements) used in accordance with the approved study protocol?**     1. ⬜ YES    2. ⬜ NO    3. COMMENTS | | | | |
| 1. **Are there any significant findings in this visit that could affect participant’s/subject’s rights, safety or welfare**     1. ⬜ YES    2. ⬜ NO    3. COMMENTS | | | | |
| 1. **Overall, does the study site provide adequate protection for the rights, safety or welfare of study participants/subjects?**     1. ⬜ YES    2. ⬜ NO    3. COMMENTS | | | | |
| 1. **How well are study participants/subjects protected?**     1. ⬜ GOOD    2. ⬜ FAIR    3. ⬜ NOT GOOD    4. COMMENTS | | | | |
| 1. **Are there further actions or queries resulting from this site visit?**     1. ⬜ YES    2. ⬜ NO    3. COMMENTS | | | | |
| **13. Additional remarks** | | | | |
| **14. Duration of visit:** <hours >**/** From <hh:mm> to <hh:mm> | | | | |
| **COMPLETED BY THE FOLLOWING EVHRDC ERC MEMBER/ REPRESENTATIVES:** | | | | |
| **NAME** | | **SIGNATURE** | | **DATE** |
| Name 1 | |  | | <dd/mm/yyyy> |
| Name 2 | |  | | <dd/mm/yyyy> |
| Name 3 | |  | | <dd/mm/yyyy> |

| **RECOMMENDED ACTION:** (For ERC use only)   * UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION * REQUEST INFORMATION: (specify) * RECOMMEND FURTHER ACTION: (specify) |
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| **SITE VISITING TEAM**  Signature  **SECRETARY** |
| Date: <dd/mm/yyyy> Name <Title, Name, Surname> |
| **SITE VISITING TEAM**  Signature  **CHAIR** |
| Date: <dd/mm/yyyy> Name <Title, Name, Surname> |