Form 14.2 Progress Report

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

***PROGRESS REPORT***

|  |  |  |  |
| --- | --- | --- | --- |
| **Protocol No.** |  | **Approval Date** |  |
|  |  |  |  |
| **Protocol Title** |  |
|  |  |  |  |
| **Investigator** |  | **Sponsor** |  |
|  |  |  |  |
| ACTION REQUESTED:  ☐Renew - New participant accrual to continue  ☐Renew - Enrolled participant follow up only  ☐Renew - Completion of protocol requirements  ☐Terminate - Protocol discontinue |
|  |  |  |  |
| Any amendments since the last review? (Describe briefly) ☐ No ☐ Yes |
|  |
| Any change in participant population, recruitment or selection ☐ No ☐ Yes Criteria since the last review? (Explain the changes) |
|  |
| Any change in the Informed Consent process or documentation since ☐ No ☐ Yes The last review? (Please explain) |
|  |
| Is there any new information in recent literature or similar research ☐ No ☐ Yes That may change the risk/benefit ratio for participants in the study? (Discuss and attach a narrative |
|  |
| Any unexpected complications or side effects noted since the last Review? ☐ No ☐ Yes (Discuss and attach a narrative) |
|  |
| Did any participant withdraw from this study since the last approval? ☐ No ☐ Yes (Reasons for withdrawal |
|  |
| Any new investigator that has been added to or removed ☐ No ☐ Yesfrom the Research Team since the last review? |
|  |
| (Please identify them and submit The CVs of new investigators.) |
|  |
| Summary of protocol participants  ☐ Accrual ceiling set by ERC \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ New participants accrued since last review \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Total participants accrued since protocol began \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |
| Accrual Exclusions  ☐ None  ☐ Male  ☐ Female  ☐ Others (Specify) |
|  |
| Are there any new collaborating sites that have been added or ☐ No ☐ Yes Deleted since the last review? Please identify the sites and note the Addition or deletion |
|  |
| Impaired Participants ☐ None  ☐ Physically \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Cognitively\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Both \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

***To be filled out by EVHRDC-ERC***

|  |  |
| --- | --- |
| Date received: |  |
| Received by: | Signature: |
| Primary Reviewers:12Name of other reviewer/s12 | Signature | Date |
| Recommendations:☐ Approve ☐ Request an amendment to the review  protocol or the consent form ☐ Request further information Date of meeting ☐ Suspend or terminate the study \_\_\_\_\_\_\_\_\_\_ ☐ Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Type of Review: ☐ Expedited review☐ Full Board | Date of Meeting: |
|  |  |  |
| Change to the protocol recommended? ☐ No ☐ Yes |
|  |
| Changes to the informed consent form recommended? ☐ No ☐ Yes Comments: |
|  |
| ERC Final Decision: |
|  |
| Certified by:ERC Chair: Signature: Date: |