Form 18.1 Continuing Review Application

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

***CONTINUING REVIEW APPLICATION***

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:** *Ethical clearance or approval is granted for a period of one year. Continuing review is required to be done at least once a year, corresponding to the risk assessment of the study protocol. The frequency of continuing review is indicated in the Study Protocol Approval Letter. For ethical clearance or approval approaching the one-year expiry date and requiring a renewal or extension, it is advisable to submit this form 60 days prior to expiry date.*

| **PROTOCOL CODE:**  |
| --- |
| **STUDY PROTOCOL TITLE:**  |
| **APPROVAL DATE:** <dd/mm/yyyy> |
| **PRINCIPAL INVESTIGATOR:**  |
| **Email:**  | **Telephone:**  | **Mobile:**  |
| **STUDY SITE:**  |
| **STUDY SITE ADDRESS:**  |
| **SPONSOR:**  |
| **SPONSOR CONTACT PERSON:**  |
| **Email:**  | **Telephone:**  | **Mobile:**  |
| **APPLICATION SUBMISSION DATE:** (to be filled out by ERC) <dd/mm/yyyy> |
| 1. **START DATE:**

*☐*1.1 Date of research site initialization: <dd/mm/yyyy> *☐*1.2 Explanation, if not yet initialized as of date of this application: <reason/s> |
| 1. **ACTION REQUESTED:**

*☐*2.1 Renewal: New participant accrual to continue*☐*2.2 Renewal: Enrolled participant follow up only*☐*2.3 Early Termination: Study protocol discontinued ahead of study indicated duration |
| 1. **HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW/APPROVAL?**

*☐*3.1 No *☐*3.2 Yes (Describe briefly and indicate date/s of Study Protocol Amendment Submission/s) |
| 1. **SUMMARY OF STUDY PROTOCOL PARTICIPANTS**:
 |
| <number>  | Accrual ceiling set by the Panel  |
| <number>  | New participants accrued since last review/approval  |
| <number>  | Total participants accrued since study protocol began  |
| 1. **ACCRUAL EXCLUSIONS**

*☐*None*☐*Male*☐*Female*☐*Other (specify):  |
| 1. **IMPAIRED PARTICIPANTS**

*☐*None*☐*Physically*☐*Cognitively*☐*Both |
| 1. **HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION,**

**RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW/APPROVAL?** *☐*7.1 No*☐*Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s ) |

| 1. **HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW/ APPROVAL? Attach latest version of participant information sheet and informed consent form/document**

*☐*8.1 No *☐*8.2 Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)  |
| --- |
| 1. **HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT THE PANEL’S EVALUATION OF THE RISK/BENEFIT ASSESSMENT OF HUMAN PARTICIPANTS INVOLVED IN THIS STUDY PROTOCOL?**

*☐*9.1 No *☐*9.2 Yes **(**Describe briefly and provide copy of literature cited, including the Investigator’s Brochure if applicable**)**  |
| 1. **HAVE ANY UNEXPECTED DISCOMFORTS, COMPLICATIONS, OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW/ APPROVAL?**

 *☐*10.1 No  *☐*10.2 Yes (Summarize and indicate date/s of SUSAR report submission/s **)**  |
| 1. **HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST REVIEW/APPROVAL?**

 *☐* 11.1No *☐* 11.2 Yes (Explain context surrounding withdrawal and documenting due diligence exerted by the study team in managing these withdrawals) |
| 1. **HAVE THERE BEEN NEW/ADDITIONAL INVESTIGATIONAL NEW DRUG/DEVICE**

**REGISTRATIONS ASSOCIATED WITH THIS STUDY SINCE THE LAST REVIEW/APPROVAL?** (Indicate registration information)  *☐* None FDA Registration No.  *☐* IND Product Name:  *☐* IDE Sponsor:  Holder:  |
| 1. **HAVE THERE BEEN ANY NEW INTERVENTION(S) OR METHODS IN THE CONDUCT OF STUDY THAT IS/ARE NOT IN THE APPROVED PROTOCOL**

*☐*13.1 No *☐*13.2 Yes (Describe use and indicate date/s of Study Protocol Deviation/NonCompliance/Violation Report Submission/s)  |
| 1. **HAVE ANY INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW/ APPROVAL?**

*☐*14.1 No *☐*14.2 Yes (Enumerate personnel and indicate date/s of Study Protocol Amendment Submission/s. Append CV if not yet submitted to the UPMREB Review Panel)  |
| 1. **HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW/ APPROVAL?**

*☐*15.1 No *☐*15.2 Yes (Enumerate sites and indicate date/s of Study Protocol Amendment Submission/s)  |
| 1. **HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A PARTY RELATED TO THIS STUDY PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST SINCE THE LAST REVIEW/ APPROVAL?**

*☐*16.1 No *☐*16.2 Yes (Append a statement of disclosure)  |
| 1. **HAVE THERE BEEN CHANGES IN STUDY PERSONNEL SINCE THE LAST REVIEW/ APPROVAL?**

*☐*17.1 NONE: *☐*17.2 DELETED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s )  *☐*17.3 ADDED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s)  |
| 1. **HAVE THERE BEEN OTHER CHANGES NOT MENTIONED ABOVE SINCE THE LAST REVIEW/APPROVAL? Attach protocol synopsis.**

*☐*18.1 No *☐*18.2 Yes **(**Describe changes and indicate date/s of Study Protocol Amendment Submission/s) |
| **SIGNATURE OF PRINCIPAL INVESTIGATOR:**  |
| **DATE SIGNED:** <dd/mm/yyyy> |

| RECOMMENDED ACTION: * Grant renewal of the ethical clearance

 Duration of Approval: from mm/dd/yyyy to mm/dd/yyyy* Not grant the renewal of ethical clearance

Reason: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* ERC requests for other documents to be able to make the decision to grant renewal
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| --- |
| **ERC MEMBER SECRETARY**  Signature  |
| Date: <dd/mm/yyyy> Name <Title, Name, Surname>  |
| **ERC CHAIR**  Signature  |
| Date: <dd/mm/yyyy> Name <Title, Name, Surname>  |