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 |
| --- |
| **ERC MEMBER SECRETARY**  Signature |
| Date: <dd/mm/yyyy> Name <Title, Name, Surname> |
| **ERC CHAIR**  Signature |
| Date: <dd/mm/yyyy> Name <Title, Name, Surname> |