****

**Continuing Review Form (CRF)**

**INSTITUTIONAL ETHICS COMMITTEE (IEC)**

|  |  |  |  |
| --- | --- | --- | --- |
| STUDY TITLE: | | | |
| ETHICS APPROVAL CODE: | | | |
| NAME OF PRINCIPAL INVESTIGATOR: | | | |
| SITE OF STUDY: | | | |
| DATE OF INITIAL ETHICAL APPROVAL: | | DATE OF LAST ETHICAL RENEWAL: | |
| EXPECTED STUDY DURATION (Including Recruitment Period) FROM DATE OF INITIAL ETHICAL APPROVAL: | | | |
| CURRENT STUDY STATUS. CHECK ALL THAT APPLY:  Study has not been initiated/ is put on hold. Kindly JUSTIFY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Data Collection  Data Analysis  Active Enrollment  Closed Enrollment | | | |
| **PLEASE SELECT EITHER ONE:** | | | |
| (A) SUMMARY OF STUDY SUBJECTS (APPLICABLE FOR STUDIES WITH INFORMED CONSENT): | | (B) SUMMARY OF STUDY DATA (IF WHERE APPLICABLE): | |
|  | Targeted number of subjects/ participants approved by IEC |  | Targeted number of records/ biological specimens/ data approved by IEC |
|  | Number of new subjects enrolled since initial approval / last annual renewal |  | Number of records/ biological specimens/ data accessed |
|  | Total number subjects enrolled since study was initiated. | No Data Collection/ Assessment till Date.  Reason: | |
| No Enrollment to Date. Reason: | |
| HAS ANY SUBJECT WITHDRAWN/ TERMINATED FROM THIS STUDY SINCE THE LAST IEC INITIAL APPROVAL/ RENEWAL?  NOT APPLICABLE  NO  YES. KINDLY JUSTIFY (in table below)   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Subject Study ID** | **Study Site Name** | **Withdrawn / Terminated (W/T)** | **Date Withdrawn / Terminated** | **Reason/ Description of withdrawal/ Termination** | **Actions taken to ensure subject’s safety** | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | | | | |
| HAS THERE BEEN ANY CHANGE IN THE SUBJECT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST IEC INITIAL APPROVAL/ RENEWAL?  NO  YES. EXPLAIN: | | | |
| HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT IEC’S EVALUATION OF THE RISKS / BENEFITS ON HUMAN SUBJECTS INVOLVED IN THIS STUDY SINCE THE LAST IEC INITIAL APPROVAL/ RENEWAL? (Eg: Investigator Brochure, Data Safety Monitoring Board Report, etc)  NOT APPLICABLE  NO  YES. EXPLAIN:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **SUMMARY** | **STUDY DOCUMENTS UPDATED? (YES/ NO)** | **DOCUMENT(S) UPDATED (with Version Number/ Date)** | **Date Approved/ Acknowledged by IEC** | **Additional Remarks** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | | | | |
| HAS ANY UNEXPECTED COMPLICATION OR SIDE EFFECT BEEN NOTED SINCE THE LAST IEC INITIAL APPROVAL/ RENEWAL?  NOT APPLICABLE  NO  YES. KINDLY JUSTIFY (in table below)   |  |  |  |  | | --- | --- | --- | --- | | **SUSAR / INVESTIGATOR BROCHURE (with Version Number/ Date if applicable)** | **Site Name (if SUSAR occurred at a local site)** | **Summary of Complications/ Side Effects** | **Date Approved/ Acknowledged by IEC** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | | | | |
| HAS THERE BEEN ANY CHANGE IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST IEC INITIAL APPROVAL/ RENEWAL?  NOT APPLICABLE  NO  YES (Explain changes in the table below)   |  |  |  | | --- | --- | --- | | **Informed Consent Form with Version Number/ Date** | **Summary of Changes** | **Date Approved by IEC** | |  |  |  | |  |  |  | |  |  |  | | | | |
| HAS ANY CO- / SITE INVESTIGATORS BEEN ADDED OR REMOVED SINCE THE LAST IEC INITIAL APPROVAL/ RENEWAL?  NO  YES (Identify all changes in the table below)   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Investigator’s Name** | **Study Site** | **Role (Principal Investigator/ Sub- Investigator) – PI/ SI** | **Added/ Removed** | **Date Approved by IEC** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | | | | |
| HAS THERE BEEN ANY OTHER AMENDMENT (OTHER THAN THE ONES LISTED ABOVE) SINCE THE LAST IEC INITIAL APPROVAL/ RENEWAL?  NO  YES (Explain changes in table below)   |  |  | | --- | --- | | **Summary of Amendments** | **Date Approved by IEC** | |  |  | |  |  | |  |  | | | | |
| HAS ANY INVESTIGATOR DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS STUDY WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST SINCE THE LAST IEC INITIAL APPROVAL/ RENEWAL?  NO  YES (Append a statement of disclosure) | | | |
| AS THERE BEEN ANY PROTOCOL DEVIATION (PD)/ PROTOCOL VIOLATION (PV) REPORTED TO IEC INVOLVING THE IEC APPROVED SITES SINCE THE LAST IEC INITIAL APPROVAL/ RENEWAL?  NOT APPLICABLE  NO  YES. (Summarise in the table below)   |  |  |  |  | | --- | --- | --- | --- | | **Subject Study ID** | **Study Site Name** | **Brief Description of Protocol Deviation** | **Date Reported to IEC** | |  |  |  |  | |  |  |  |  | |  |  |  |  | | | | |
| HAS THERE BEEN ANY SERIOUS ADVERSE EVENT (SAE) REPORTED TO IEC INVOLVING THE IEC APPROVED SITES SINCE THE LAST IEC INITIAL APPROVAL/ RENEWAL?  NOT APPLICABLE  NO  YES. (Summarise in the table below)   |  |  |  |  | | --- | --- | --- | --- | | **Subject Study ID** | **Study Site Name** | **Brief Description of SAE** | **Date Reported to IEC** | |  |  |  |  | |  |  |  |  | |  |  |  |  | | | | |
| HAS THE STUDY TRIAL INSURANCE BEEN UPDATED SINCE THE LAST IEC INITIAL APPROVAL/ RENEWAL?  NOT APPLICABLE  NO  YES   |  |  |  | | --- | --- | --- | | **Trial Insurance Policy No** | **Date of Expiry** | **Date Approved by IEC** | |  |  |  | | | | |
| Is this Continuing Review Form (CRF) being submitted past the expiration date of IEC ethical approval?  NO  YES  If you are submitting this CRF after the expiration date of IEC ethical approval, were research-related activities conducted during the time IEC approval of this research was expired?  No  Yes, EXPLAIN what activities were conducted: | | | |
| **I DECLARE THAT THE INFORMATION PROVIDED ABOVE IS TRUE & CORRECT TO THE BEST OF MY UNDERSTANDING**  COMPLETED BY:  …………………………………………………..  NAME:  (CORRESPONDING PRINCIPAL INVESTIGATOR)  DATE: | | | |