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**Continuing Review Form (CRF)**

**INSTITUTIONAL ETHICS COMMITTEE (IEC)**

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| 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| HAS ANY SUBJECT WITHDRAWN/ TERMINATED FROM THIS STUDY SINCE THE LAST IEC INITIAL APPROVAL/ RENEWAL?[ ]  NOT APPLICABLE[ ]  NO[ ]  YES.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)

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| **Subject Study ID** | **Study Site Name** | **Withdrawn / Terminated (W/T)** | **Date Withdrawn / Terminated** | **Reason/ Description of withdrawal/ Termination** | **Actions taken to ensure subject’s safety** |
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| 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:

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| **SUMMARY** | **STUDY DOCUMENTS UPDATED? (YES/ NO)** | **DOCUMENT(S) UPDATED (with Version Number/ Date)** | **Date Approved/ Acknowledged by IEC** | **Additional Remarks** |
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| 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)

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| **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** |
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| 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)

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| **Informed Consent Form with Version Number/ Date** | **Summary of Changes** | **Date Approved by IEC** |
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| 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)

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| **Investigator’s Name** | **Study Site** | **Role (Principal Investigator/ Sub- Investigator) – PI/ SI** | **Added/ Removed** | **Date Approved by IEC** |
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| 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)

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| **Summary of Amendments** | **Date Approved by IEC** |
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| 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)

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| **Subject Study ID** | **Study Site Name** | **Brief Description of Protocol Deviation** | **Date Reported to IEC** |
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| 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)

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| **Subject Study ID** | **Study Site Name** | **Brief Description of SAE** | **Date Reported to IEC** |
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| HAS THE STUDY TRIAL INSURANCE BEEN UPDATED SINCE THE LAST IEC INITIAL APPROVAL/ RENEWAL?[ ]  NOT APPLICABLE[ ]  NO[ ]  YES

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| **Trial Insurance Policy No** | **Date of Expiry** | **Date Approved by IEC** |
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| Is this Continuing Review Form (CRF) being submitted past the expiration date of IEC ethical approval?[ ]  NO[ ]  YESIf 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:  |