|  |
| --- |
| **(Annexure 3)****Continuing Review/ Annual report format** |
| (*Logo of the institute)* |  (*Name of the institute)***EC Ref. No*. (****for office use****) \_\_\_\_\_\_\_\_***  |

|  |
| --- |
| ***\*The annual report must be duly submitted no later than 30 days before the annual year's completion.*** |
| Title of study:       Principal Investigator (Name, Designation and Affiliation)       |

|  |  |  |
| --- | --- | --- |
|  | EC Reference No.:       |  |
|  | Date of EC Approval: Click here to enter a date. | Duration of Approval       months/ years |
|  | Date of Start of study: Click here to enter a date. | Proposed date of Completion: Click here to enter a date. |
| Period of Continuing ReportClick here to enter a date. | To Click here to enter a date. |
|  | Does the study involve recruitment of participants? Yes  No  1. If yes, Total number expected      No. Screened:      No. Enrolled:

  Number Completed:       No. on followup:       .1. Enrolment status – ongoing / completed/ stopped
2. Report of DSMB*16* Yes  No NA
3. Any other remark
 |
|  | 1. Have any participants withdrawn from this study since the last approval? Yes  No  NA

 If yes, total number withdrawn and reasons:       |
|  | Is the study likely to extend beyond the stated period*17*? Yes  No  If yes, please provide reasons for the extension      |
|  | Have there been any amendments in the research protocol/informed consent document (ICD) during the past approval period? **If No, skip to item no.6**  Yes  No  |
| (a) If yes, date of approval for protocol and ICD : Click here to enter a date. |
|  | (b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? If yes, when / how:       Yes  No  |

*16In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.*

*17Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

|  |  |
| --- | --- |
|  | Is any new information available that changes the benefit -risk analysis of human participants involved in this study? Yes  No If yes, discuss in detail:       |
|  | Have any ethical concerns occurred during this period? Yes  No  If yes, give details       |
|  | (a) Have any adverse events been noted since the last review? Yes  No   Describe in brief:      (b) Have any SAE’s occurred since last review? Yes  No   If yes, number of SAE’s :       Type of SAE’s:      (c) Is the SAE related to the study? Yes  No   Have you reported the SAE to EC? If no, state reasons Yes  No         |
|  | Has there been any protocol deviations/violations that occurred during this period? If yes, number of deviations      Have you reported the deviations to EC? If no, state reasons Yes  No         |
|  | In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC Yes  No  NA  |
|  | Are there any publications or presentations during this period? If yes give details Yes  No       |
|  | Brief Summary of the Study (up to 500 words) (to briefly describe the status, findings, activities undertaken, any deviations or changes, special mentions etc.)      |

 Signature of PI:  Click here to enter a date.