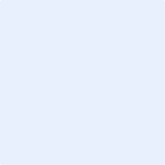
|  |  |
| --- | --- |
|  | **(Annexure 14)**  **Logo of the Institute**  **Project extension form**    ***(Name of the Institution)***  **EC Ref. No*.(****for office use):* |

|  |
| --- |
| ***\*The project extension must be duly submitted no later than 30 days before the approval expires.*** |
| 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. | Date of Completion: Click here to enter a date.  *(As per the first approval granted)* | |
| Duration of Extension sought:       months/ years |  | |
| Period of Extension sought from Click here to enter a date. | To Click here to enter a date. | |
|  | | Have there been any modifications in the budget for the extension sought?  **If No, skip to item no.5**  Yes  No  If yes, discuss in detail: | | |
|  | | Does the study involve recruitment of participants? Yes  No   1. If yes, Total number for study       No. 2. Screened:       No. Enrolled:       No. 3. Number Completed:       No. on followup:       No. 4. Enrolment status – ongoing / completed/ stopped       No. 5. If ongoing , Expected       No. 6. Report of DSMB\* Yes  No NA   *\* In 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.*   1. 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 Have any participants withdrawn from this study since the last approval? Yes  No  NA   If yes, total number withdrawn and reasons: | | |
|  | | Have there been any amendments in the research protocol/informed consent document (ICD) for the extension sought? Yes  No  **If No, skip to item no.7** | | |
| (a) If yes, discuss in detail: | | |
|  | | (b) In case of amendments in the research protocol/ICD, will re-consent be sought from participants?  If yes, when / how:       Yes  No | | |
|  | | 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 the study? 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 the period of study?  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 | | |
|  | | Briefly explain the reason for the extension sought (up to 500 words) (Please attach the relevant documents in support of the extension.) | | |

Signature of PI:  Click here to enter a date.