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

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| ***\*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)       |

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|  | 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
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|  | 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 Have any participants withdrawn from this study since the last approval?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 If yes, total number withdrawn and reasons:       |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.