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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) |

(Annexure 14)

Application Form for Project extension

Institute Ethics Committee

National Institute of Technology Meghalaya

**EC Ref. No.** *(For office use):*



|  |  |  |
| --- | --- | --- |
|  | EC Reference No: \_\_\_\_\_\_\_\_\_\_\_\_\_  |  |
|  | Date of EC Approval:  | Duration of Approval months/ years |
|  | Date of Start of study:  | Date of Completion: *(As per the first approval granted)* |
| Duration of Extension sought: months/ years |  |
| Period of Extension sought from  | To  |
|  | 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 Have any participants withdrawn from this study since the last approval?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 If yes, total number withdrawn and reasons:  |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:

Date: