## (Annexure 14)

# Project extension form

**Logo of the Institute**

***(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:<br><br>Principal Investigator (Name, Designation and Affiliation) |

| | | |
|---|---|---|
| 1. | EC Reference No: _____ | |
| 2. | Date of EC Approval: Click here to enter a date. | Duration of Approval months/ years |
| 3. | Date of Start of study: Click here to enter a date. | Date of Completion: Click here to enter a date.<br>*(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. |
| 4. | Have there been any modifications in the budget for the extension sought?<br>**If No, skip to item no.5** Yes ☐ No ☐<br>If yes, discuss in detail: | |
| 5. | Does the study involve recruitment of participants? Yes ☐ No ☐<br>(a) If yes, Total number for study No.<br>(b) Screened: No. Enrolled: No.<br>(c) Number Completed: No. on followup: No.<br>(d) Enrolment status – ongoing / completed/ stopped No.<br>(e) If ongoing , Expected No.<br>(f) Report of DSMB* Yes ☐ No ☐ NA ☐<br>** 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.*<br>(g) Any other remark | |

| | |
|---|---|
| | (h) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA ☐<br>If yes, total number withdrawn and reasons: |
| 6. | Have there been any amendments in the research protocol/informed consent document (ICD) for the extension sought? Yes ☐ No ☐<br>**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?<br>If yes, when / how: Yes ☐ No ☐ |

7. 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:

8. Have any ethical concerns occurred during the study? Yes ☐ No ☐

   If yes, give details

9. (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 ☐

10. 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 ☐

11. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC

    Yes ☐ No ☐ NA ☐

12. Are there any publications or presentations during this period? If yes give details Yes ☐ No ☐

13. 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.