Annexure 11. Continuing Review/Annual Report

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

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC Approval: Click here to enter a date. Validity of approval: Click here to enter a date.
2. Date of Start of study: Click here to enter a date. Proposed date of Completion: Click here to enter a date.

   Period of Continuing Report Click here to enter a date. ---- to ------ Click here to enter a date.
3. Does the study involve recruitment of participants? Yes ☐ No ☐

   (a) If yes, Total number expected No. Screened: No. Enrolled:

   Number Completed: No. on followup: .

   (b) Enrolment status – ongoing / completed/ stopped

   (c) Report of DSMB* *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.*

   Yes ☐ No ☐ NA ☐

   (d) Any other remark

   (e) Have any participants withdrawn from this study since the last approval?

   Yes ☐ No ☐ NA ☐

   If yes, total number withdrawn and reasons:
4. Is the study likely to extend beyond the stated period?
   (Mention problems if encountered) Yes ☐ No ☐

   If yes, please provide reasons for the extension

5. 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? Yes ☐ No ☐
If yes, when / how:

6. 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:

7. Have any ethical concerns occurred during this period? Yes ☐ No ☐
If yes, give details

8. (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 ☐

9. 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 ☐

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

    Yes ☐ No ☐ NA ☐

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

    Any other comments:

Signature of PI:

Click here to enter a date.