AX03/SOP12/V1

Continuing Review Application Form for Progress report

Date:

CEC No. of the Project:

Study Title:

Principal Investigator (Name, Designation & Affiliation):

1. Date of CEC Approval:
2. Date of Start of Study: Proposed Date of Completion:

   Period of Continuing Report: …… to:

   ……..
3. Does the study involve recruitment of participants? If yes,
   No. of participants approved by CEC :
   No. of participants recruited: No. of participants ongoing:
   No. of participants completed: No. of refusal to consent
   No. of participants dead :
   No. of participants withdrawn.
   If yes, reasons for drop-outs for each participant, attach separate sheet if needed

4. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during this continuing review period? Yes ☐ No ☐

   If No, Skip to point no. 5

   a. If Yes, date of approval for Protocol and ICD;
      ……
   b. In case of amendment in the ICD was re-consent sought from participants?

      Yes ☐ No ☐

      If yes, state the number: ……

5. Is any new information available in the literature, or evolved from this or similar research that might change the CEC's evaluation of the risk/benefit analysis of participants involved in this protocol? Yes ☐ No ☐

   If yes, discuss in detail (attach separate sheet if needed)

6. Have any ethical concerns occurred during this continuing review period

   Yes ☐ No ☐

   If yes, give details:

7. a. Have any adverse events been noted during this continuing review period?

   Yes ☐ No ☐

If yes, state the number:

b. Have any SAE occurred during this continuing review period? Yes ☐ No ☐

If yes, number of SAE:

a. Have you reported the SAE to EC during this continuing review period?
Yes ☐ No ☐

d. Was causality determined by CEC as related ☐ or not related ☐

If related, what was the compensation given ……..

e. In case of multicentric trials, whether reports of SAEs at other sites have been submitted to the CEC……

8. Has any protocol deviations/violations occurred during this continuing review period?
Yes ☐ No ☐ If yes, number of deviations

Have you reported the deviations to CEC? Yes ☐ No ☐

9. Have there been any amendments in the protocol/Informed Consent Document since the last review? Yes ☐ No ☐

a. Were these protocol/Informed Consent Document (ICD) amendments approved by CEC? Yes ☐ No ☐

If no, mention the amendments not approved

b. At present which protocol amendment (version) is being followed at the site

c. At present which ICD amendment (version) is being followed at the site

d. Were these protocol/Informed Consent Document (ICD) amendments approved by CEC? Yes ☐ No ☐

10. Have any participating investigators been added or withdrawn since last review?
Yes ☐ No ☐

If Yes (Identify all changes in the attached narrative)

11. Is report of interim data analysis available? Yes ☐ No ☐

If Yes (submit as an attachment)

12. Is report of the data safety and monitoring board available? Yes ☐ No ☐

13. Are there any publications or presentations during this continuing review period?
Yes ☐ No ☐

If yes, give details ……

Signature of the Principal Investigator with Date: