Continuing Review

1. Title of study……

……

2. Principal Investigator (Name, Designation and Affiliation): ……..

……

3. Date of IEC approval: …….

4. Validity of approval: ……

5. Date of start of study: ……..

6. Proposed date of study completion: ……

7. Period of continuing report from to: ……...

8. Does the study involve recruitment of participants Yes- No-

(a) If yes, Total number expected:

Number Screened: …….. Number Enrolled: …….

Number Completed: …… Number on follow up: ……

(b) Enrolment status – ongoing / completed/stopped

(c) Report of DSMB 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(e) Have any participants withdrawn from this study since the last approval?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If yes, total number withdrawn and reasons: ……

9. Is the study likely to extend beyond the stated period? Yes No

If yes, please provide reasons for the extension……

10. Have there been any amendments in the research protocol/Informed Consent Form (ICF) during the past approval period? If No, skip to item no. 9- Yes No

(i) If yes, date of approval for protocol and ICF:

(ii) In case of amendments in the research protocol/ICF, was re-consent sought from participants? Yes No If yes, when/how: ……

11. 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: ……..

…….

…….

12. Have any ethical concerns occurred during this period? Yes No

If yes, give details ……

……..

……..

13. Have any adverse events been noted since the last review? Yes No

Describe in brief: …….

……..

14. (a) Have any SAE's occurred since last review? Yes No

If yes, number of SAE's Type of SAE's:…….

……..

(b) Is the SAE related to the study? Yes No

(c) Have you reported the SAE to IEC? Yes No . If no, state reasons……

…….

15. a). Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations……

b) Have you reported the deviations to IEC? Yes No

If no, state reasons……...

……..

16. In case of multicentre trials, have reports of off-site SAEs been submitted to the IEC? Yes No NA

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

Any other comments:

Signature of PI / Research scholar

(in case of research scholar)

Signature of Guide