Project Extension Form

The project extension must be duly submitted no later than 30 days before the approval expires.

1. Title of the study……
   ……...
2. Principal Investigator (Name, Designation and Affiliation)
   ……
3. EC reference number……..
4. Date of EC approval……
5. Duration of approval……...
6. Date of start of study……...
7. Date of completion……..
8. Period of extension sought from……to……..
9. Have there been any modifications in the budget for the extension sought? Yes/ No
   If yes, give details……
   ……
   ……
10. Does the study involve recruitment of participants? Yes /No
    If yes,

(i) Total number of participants for study-

(ii) Screened-

(iii) Enrolled-

(iv) Number Completed-

(v) On follow up-

(vi) Enrolment status – ongoing / completed/ stopped-

(vii) If ongoing, expected no. –

(viii) 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.

(ix) Have any participants withdrawn from this study since the last approval?

Yes/ No /NA

If yes, total number withdrawn and reasons:……..

……..

……..

(x) Any other remark

11. 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.12

(i) If yes, give details ……..

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(ii) In case of amendments in the research protocol/ICD, will re-consent be sought from participants? Yes/ No

If yes, when / how: ……

……

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12. Is any new information available that changes the benefit -risk analysis of human participants involved in this study? Yes / No

If yes, give details……

……:

13. Have any ethical concerns occurred during the study? Yes/ No

If yes, give details……

……..

14. (i) Have any adverse events been noted since the last review? Yes/No

Describe in brief ……

……

(ii) Have any SAEs occurred since last review? Yes/No

If yes, number of SAEs…….....

Type of SAEs……

(iii) Is the SAE related to the study? Yes/No

15. Have you reported the SAE to EC? Yes/No

If no, state reasons …….

…….

16. Has there been any protocol deviations/violations that occurred during the period of study? Yes/ No

If yes, number of deviations ……

Have you reported the deviations to EC? Yes/No

If no, state reasons ……..

…….

17. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC? Yes/No/NA

18. Are there any publications or presentations during this period? Yes/No

If yes, give details……

…….

19. Briefly explain the reason for the extension sought (up to 500 words) (Please attach the relevant documents in support of the extension.)

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Signature of PI

Date: