Periodic / Continuing Review

Yenepoya Ethics Committee-3 (YEC-3)

EC Ref. No. *(For office use)*

Title of study: .....

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

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1. Date of EC Approval: dd mm yy Validity of approval: dd mm yy
2. Date of Start of study: dd mm yy Proposed date of Completion: dd mm yy

   Period of Continuing Report: dd mm yy ---- to ------ dd mm yy
3. Does the study involve recruitment of participants? Yes ☐ No ☐

   (a) If yes, Total number expected..... Number Screened: ..... Number Enrolled: .....

   Number Completed:..... Number on followup:.....

   (b) Enrolment status – ongoing / completed/ stopped

   (c) Report of DSMB[1] Yes ☐ No ☐ NA ☐

   (d) Any other remark.....

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   (e) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA ☐

   If yes, total number withdrawn and reasons: .....

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   .....
4. Is the study likely to extend beyond the stated period ?[2] Yes ☐ No ☐

   If yes, please provide reasons for the extension. .....

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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: dd mm yy

   (b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐ No ☐

   If yes, when / how: .....

   .....

   .....

Note: ICD - informed consent document

[1] *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.*

[2] *Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

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: .....

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

If yes, give details:.....

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8. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐

Describe in brief: .....

.....

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(b) Have any SAE's occurred since last review? Yes ☐ No ☐

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

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(c) Is the SAE related to the study? Yes ☐ No ☐

Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐

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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 ☐

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10. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ? Yes ☐ No ☐ NA ☐

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

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Any other comments:.....

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Signature of PI: ..... dd mm yy