

Institutional Ethics Committee
Institute of Human Behaviour & Allied Sciences, Delhi

Version 2; 31 May, 2022

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(e) Have any participants withdrawn from this study since the last approval?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If yes, total number withdrawn and reasons: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

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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 : [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 ☐

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

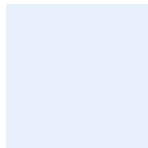
Yes ☐ No ☐ NA ☐

11. Are there any publications or presentations during this period?
If yes give details

Yes ☐ No ☐

Any other comments:

Signature of PI:



[Click here to enter a date.](#)