



(Annexure 3)

Continuing Review / Annual report format

Institute Ethics Committee
Indian Institute of Technology, Delhi

EC Ref. No. (For office use):

Title of study:

.....

..... 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 DSMB¹⁶

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(e) Have any participants withdrawn from this study since the last approval?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If yes, total number withdrawn and reasons: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 ?¹⁷

Yes ☐ No ☐

If yes, please provide reasons for the extension.

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:

¹⁶In 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.

¹⁷Problems 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:

.....

.....

(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
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