(Annexure 3)

Continuing Review / Annual report format

Institute Ethics Committee

Indian Institute of Technology, Delhi

**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:
2. Date of Start of study:

Validity of approval: Proposed date of Completion:

Period of Continuing Report:

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

1. Does the study involve recruitment of participants?

---- to ------

Yes  No 

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

* 1. If yes, Total number expected…………………… Number Screened: …………………… Number Enrolled: ………................

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

* 1. Enrolment status – ongoing / completed/ stopped
	2. Report of DSMB16 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(e) Have any participants withdrawn from this study since the last approval? Yes  No  NA If yes, total number withdrawn and reasons: ……………………………………………………………………….....................................……..

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1. Is the study likely to extend beyond the stated period ?17 Yes  No 

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

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1. 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 

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| --- | --- | --- |
| dd | mm | yy |

* 1. If yes, date of approval for protocol and ICD :
	2. In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes  No If yes, when / how: …………………………………………………………………………………...........……………......................................................

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*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*

*Version 2.0*

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

If yes, give details:.……………………………………………………………………………………………………………………..........................................………

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

Describe in brief: …………………………………………………………………………………….......................................…….………………………………

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1. Have any SAE’s occurred since last review? Yes  No 

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

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1. 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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1. 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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1. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ? Yes  No  NA 
2. 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: ………………………………………………………….................……………………….......................………………

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| dd | mm | yy |

*Version 2.0*