(Annexure 12)

Study completion/Final 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:

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

1. Provide details of:

Date of study completion:

|  |  |  |
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| dd | mm | yy |

* 1. Total number of study participants approved by the EC for recruitment: ……………………….............................…………………

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| dd | mm | yy |

b) Total number of study participants recruited: …………………………………………………….………….................................…………………

c) Total number of participants withdrawn from the study (if any): ……………………………................................…………………..

Provide the reasons for withdrawal of participants23 : ………………………………………………………................................………………….

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1. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared) …............................................................……………………………………………………………

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1. Describe the main ethical issues encountered in the study (if any) ………………………………………..............................………………

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1. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period Deviations: …………………….........…………….. Violation: ……………………...........………… Amendments: …………………….........……….

7. Describe in brief plans for archival of records / record retention:………………..……………...............................………………………….

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*23 Explanation for the withdrawal of participants whether by self or by the PI*

*Version 2.0*

1. Is there a plan for post study follow-up? Yes  No

If yes, describe in brief: …………………………………………………………………………..........................................………………….……………………..

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1. Do you have plans for ensuring that the data from the study can be shared/ accessed easily? Yes  No If yes, describe in brief: ………………………………………………………………..................................................................................………………..

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1. Is there a plan for post study benefit sharing with the study participants? Yes  No If yes, describe in brief: …………………………………....................................…………………………………………………………………..…………………..

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11. Describe results (summary) with Conclusion 24 : ………………………………....................................……………………………….…………………

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12. Number of SAEs that occurred in the study: …………………………..................................…………………………………………….………………..

1. Have all SAEs been intimated to the EC ? Yes  No
2. Is medical management or compensation for SAE provided to the participants? Yes  No If yes, provide details……………………………………………………………………………............……….…………………………………………….…………..…..

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Signature of PI: …………………………………………………………………………………….

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| dd | mm | yy |

*24 For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.*

*Version 2.0*