INSTITUTIONAL ETHICS COMMITTEE
(DHR File No. EC/NEW/INST/2020/1079)
INDIAN INSTITUTE OF TECHNOLOGY MADRAS
Sardar Patel Road, Adyar Chennai – 600 036.
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APPLICATION FOR STUDY COMPLETION / CLOSURE REPORT

(Form to be filled by the Principal Investigator)

Title of the Research Proposal	
IITM – IEC Protocol No.	
Date of IEC Approval	
Date of start of study	
Date of study completion	
Duration of the project / trial	

1. Name of the Principal Investigator (PI) :
   Designation :
   Contact address :
   Email Id & Mobile No. :

2. Name of the Co-Investigator (Co-PI) :
   Designation :
   Contact address :
   Email Id & Mobile No. :

3. Provide details
   i. Background (250 words) :
   ii. Approved objectives (bullet points) :
   iii. Summary of results obtained :

4. Provide details of study participants
   i. Total no. of study participant approved by the EC :
   ii. Total no. of study participants screened :
   iii. Total no. of participants enrolled / recruited :
   iv. Total no. of participants withdrawn from the study :
   (provide reasons for withdrawal of participants, if any)

5. Describe in brief the publication / presentation / dissemination of information done based on the study findings (Also, mention if both positive and negative results will be shared)

6. Describe the main Ethical issues encountered in the study (if any)

7. State where there were deviations / violations / amendments made to the study protocol during the study period : Yes / No (If Yes, provide below details)
   i. No. of deviations :
   ii. No. of violations :
   iii. No. of amendments :

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

9. Is there a plan for post study follow-up with subjects? Yes / No (If yes, describe in brief)

10. Do you have plans for ensuring that the data from the study can be shared / accessed easily? Yes / No (If yes, describe in brief)

11. Is there a plan for post study benefit sharing with the study participants? Yes / No (If yes, describe in brief)

12. Where there any Serious Adverse Events (SAEs) that occurred during the study? Yes / No (If yes, state number of SAEs occurred)

13. Have all SAEs been intimated to the EC: Yes / No

14. Is medical management or compensation for SAE provided to the participants? Yes / No

15. Attach a detailed technical report with summary of the work and conclusion from this project

16. Attach a copy of published work :

17. Name of the Principal Investigator :

    Signature & Seal :

    Date :

18. Name of the Co-PI :

    Signature & Seal :

    Date :