INSTITUTIONAL ETHICS COMMITTEE
(DHR File No. EC/NEW/INST/2020/1079)
INDIAN INSTITUTE OF TECHNOLOGY MADRAS
Sardar Patel Road, Adyar Chennai – 600 036.
Email: iec@iitm.ac.in **Phone:** 044 – 2257 4929

APPLICATION FOR ANNUAL REPORT / EXTENSION REQUEST

(Form to be filled by the Principal Investigator)

Title of the Research Proposal	
IITM – IEC Protocol No.	
Date of IEC Approval	
Validity of approval	
Duration of the project / trial	
Period of continuing review	

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 of the work (250words) :
   ii. Approved objectives (bullet points) :
   iii. Brief methodology (400words) :

4. Does the study involve recruitment of participants? Yes ☐ No ☐
   i. If yes, what is the sample size approved :
   ii. No. of participants screened :
   iii. No. of participants enrolled / recruited :

5. Is participant recruitment continuing : Yes ☐ No ☐

6. Are there any dropouts? : Yes ☐ No ☐

7. Have any participants withdrawn from this study since the last approval: Yes ☐ No ☐
   (If yes, total no. withdrawn and reasons)

8. Is the study likely to extend beyond the stated period? Yes ☐ No ☐
   (If yes, provide reasons for the extension)

9. Have there been any amendments in the research protocol / informed consent document (ICD) during the past approval period? Yes ☐ No ☐
   i. If yes, date of approval for revised protocol and ICD :
   ii. In case of amendments in the research protocol / ICD, was re-consent sought from participants? Yes / No (If yes, provide details)

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10. Has there been any protocol deviations / violations that occurred during this period?
    i. If yes, number of deviations :
    ii. Have you reported the deviations to EC? If not, state reasons

11. Explain the summary of data obtained and key findings:

12. Are there any publications or presentations from the study during this period? Yes / No
    (If yes, give details and attach published paper)

13. 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)

14. Have any ethical concerns occurred during this period? Yes ☐ No ☐
    (If yes, give details)

15. Have any adverse events been noted since the last review? Yes ☐ No ☐ NA ☐
    (If yes, describe in brief)

16. Have any Serious Adverse Events (SAEs) occurred since last review? Yes ☐ No ☐ NA ☐
    (If yes, number of SAEs and type of SAEs)

17. Is the SAE related to the study? Yes ☐ No ☐

18. Have you reported the SAE to EC? Yes ☐ No ☐
    (If no, state reasons)

19. Principal Investigator :
    Signature & Seal :
    Date :

20. Co - Principal Investigator :
    Signature & Seal :
    Date :