

ANNUAL REPORT

S.No.	Title	Particulars
1a	IITM-IHEC Protocol Number	
1b	Month/ Year of approval	
1c	Number of ongoing review	
2	Title of the research proposal	
3	Name of the Principal Investigator (PI) with Qualification and Designation	
4	Name of the Co-Investigator(s) Co-PI) with Qualification and Designation	
5	Duration of the project / trial	
6	Source of funding & financial allocation for the project / trial	
7	Name of the Institute/ Dept. where research is conducted	
8a	Has participant recruitment begun?	
8b	If participant recruitment has not begun, give reasons and proceed to S. No. 18	
9	How many participants have been screened?	-
10	How many participants have been recruited?	-
11	What is the sample size required	-
12	Is participant recruitment continuing?	Yes/ No (If No, Provide a 'project report' as attachment)
13	Is there any 'drop-outs'?	Yes/ No (If Yes, Provide details)
14	Are participants still receiving active intervention?	Yes/ No (If Yes, Provide details)
15	Have there been any adverse events ? If yes, give details	Yes/ No (If Yes, Provide details)
16	Have there been any unanticipated study-related problems ? If yes, give details	Yes/ No (If Yes, Provide details)
17	Is there any new Risk/ Benefit information? If yes, give details	

18	Are there any interim changes to the protocol or consent form? If yes, give details, including submission of revised protocol and consent form for approval.	
19	Does the scientific literature indicate changes in knowledge relevant to the conduct of the study?	
20	List of attachments for review, if any	
21	Remarks, if any	
22	Signature of the Principal Investigator with date	