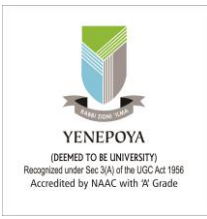


YENEPOYA ETHICS COMMITTEE 2
Yenepoya (Deemed to be University)
Floor -2(Basement), Yenepoya Dental College, Mangalore-575018
yec2@yenepoya.edu.in,(0824)2206000- Extension Number - 2063
DCGI Registration No.: ECR/1337/Inst/KA/2020
DHR registration No.: EC/NEW/INST/2023/KA/0276

YEC2/Ann01/SOP14/v1: Premature Termination Report

YEC2/Ann01/SOP14/v1
Premature Termination Report

Sl. No	Details	Responses
1	YEC 2 Protocol Number	
2	Study title	
3	Name and affiliation of Principal Investigator	
4	YEC 2 approval letter no. with date	
5	Date of last/annual/periodic status report submitted to YEC 2	
6	Date of initiation of termination/suspension/discontinuation (write date when first communication was received either from PI or Sponsor or regulatory authority or YEC 2 member)	
7	Date of communication to Chairperson/ Member-Secretary	
8	Date of conduct of extra-ordinary (emergency) meeting (if any)	
9	Date of correspondence seeking further clarification (if any)	
10	Date of receipt of clarification letter from PI	
11	Study status at time of termination/suspension/discontinuation a. Participants enrolled b. Participants completed c. Participants on-going d. Drop outs e. Participants yet to be enrolled	
12	Any serious adverse events in the study	Yes/No Comment
13	Whether the SAEs were reported to YEC 2 9on time)	Yes/No Comment
14	Brief summary of the results till date of initiation of termination	

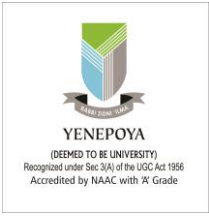


YENEPOYA ETHICS COMMITTEE 2
Yenepoya (Deemed to be University)
Floor -2(Basement), Yenepoya Dental College, Mangalore-575018
yec2@yenepoya.edu.in,(0824)2206000- Extension Number - 2063
DCGI Registration No.: ECR/1337/Inst/KA/2020
DHR registration No.: EC/NEW/INST/2023/KA/0276

15	Date of YEC 2 meeting where the termination/ suspension/discontinuation matter was discussed <i>(Note: If termination is recommended close and store the file for five years from this date. If suspension is recommended keep file open till further developments)</i>	
16	Extract of the resolution and the decision of the YEC 2 with regard to the termination/ suspension/discontinuation of the said study	
17	Date and number of the communication to the PI	
18	Date and number of the communication forwarded to the regulatory authority for information	
19	Date of protocol file closure for archiving	

Signature of the Chairperson and date:

Signature of the Member secretary and date:



YENEPOYA ETHICS COMMITTEE 2
Yenepoya (Deemed to be University)
Floor -2(Basement), Yenepoya Dental College, Mangalore-575018
yec2@yenepoya.edu.in,(0824)2206000- Extension Number - 2063
DCGI Registration No.: ECR/1337/Inst/KA/2020
DHR registration No.: EC/NEW/INST/2023/KA/0276
