

#### 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

### Yenepoya Ethics Committee 2

### Ann03/SOP10/v2

## Periodic/Continuing Review Application form

(Download the form, type the details, print, sign, scan and send to YEC2 at <a href="yec2@yenepoya.edu.in">yec2@yenepoya.edu.in</a>. Please do not delete any of the text typed in the form)

	A. Protocol details				
1	YEC2 Protocol No.				
2	Title:				
3	Type of Study				
4	Name of the Principal Investigator: Department and Institution:				
5	Names of all the Co-Is (guides):				
	Department and Institution:				
6	Names of Research Assistants/Data Coordinators				
6	Validity of approval by YEC2	From:	To:		
7	Extensions of approval (add rows for each extension)	From:	To:		
8	Protocol amendment (add rows for each amendment)	From:	То:		
9	Date for periodic review (as per YEC2 communication)				
2. Protocol timelines					
1	Date of first recruitment:				
2	Date of the last recruitment:				
3.	Participant details	Number	Date		
1	Sample size approved				



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	T				
2	Number of participants screened/date of last screened (or samples/data selected)				
3	Number of screen failures/date of last screen failure				
4	Number of participants/biological samples/data recruited/ collected				
5	Number of ongoing participants/biological samples				
6	Completed participants/date when last participant completed				
7	Participants who withdrew the consent/date of last withdrawal/or samples/data rejected				
	(Provide reasons for withdrawal/rejection)				
8	Participants who were discontinued from the study by PI or sponsor/date of last discontinuation				
	(Provide reasons for discontinuation)				
9	Participants with adverse events/dates for all adverse events				
	(Provide details of each adverse event – attach separate sheet if necessary)				
10	Number of SAE reported				
	Dates for all SAEs reported (details)				
4. Changes in the protocol/ risk to participants:					
1	Whether approved protocol version followed (provide	Yes / No			
	protocol number):	Protocol version number:			
2	Any changes made in the selection criteria of participants	Yes / No (If yes, please provide details)			



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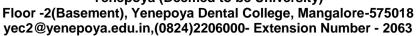


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3	Any changes made in theprotocol	Yes / No (If yes, please provide details)	
4	Any changes made in the studyteam; any change in guide	Yes / No (If yes, please provide details)	
5	Any changes in the sample size	Yes / No (If yes, please provide details)	
6	Any changes in the fundingstatus	Yes / No (If yes, please provide details)	
7	Whether approved versionfollowed: a. PIS b. ICF	Yes / No Version number	
	c. Data collection form:	-C	
8	Any increase in risk to participants based on the findings of the current study/new information in literature	Yes / No (If yes, please provide details)	
9	Any protocol deviations noted	Yes / No (If yes, please provide details)	
5	. Monitoring/ data analysis		
	Manufacture data as also is to		
1	Has interim data analysis been done?	Yes / No (If yes, provide the report)	
2	Has the data safety and monitoring board reported?	Yes / No (If yes, provide the report)	
3	Has YEC2/ regulatory authorities conducted a sitemonitoring/ audit?	Yes / No (If yes, provide the report)	
6	6. Any other:		



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1	Have any investigator(s) developed a CoI during the conduct of the study:	Yes / No (If yes, provide the report)
2	Have any research team members faced any difficulties/events during the study	Yes / No (If yes, provide the report)
3	Any other information you would like to share with the YEC2	

Signature of the PI: (with name and date)

Signature of the guide (if any): (with name and date)