

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 yec2@yenepoya.edu.in. 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 <i>(add rows for each extension)</i>	From:	To:
8	Protocol amendment <i>(add rows for each amendment)</i>	From:	To:
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		

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

3	Any changes made in the protocol	Yes / No (If yes, please provide details)
4	Any changes made in the study team; 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 funding status	Yes / No (If yes, please provide details)
7	Whether approved version followed: a. PIS b. ICF c. Data collection form:	Yes / No Version number
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		
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 site monitoring/ audit?	Yes / No (If yes, provide the report)
6. Any other:		

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)

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