

YEC2/Ann02/SOP10/v1

Continuing review application form

Name of the PI

Department:

Protocol No. _____

Title: _____

Approved by YEC 2 on _____ **Date:** _____

A	Summary of protocol participants:	
1.	No. of participants screened:	
2.	No. of participants approved by YEC 2:	
3.	No. of recruited participants:	
4.	No. of ongoing participants:	
5.	No. of completed participants:	
6.	No. of participants who refused to consent:	
7.	Have any participants been withdrawn from this study?	Yes <input type="checkbox"/> No <input type="checkbox"/>
8.	If Yes, (state the number and reasons for drop-outs of each participant, attach separate sheet if needed)	
B	Amendments in the protocol	
9.	Have there been any amendments in the protocol or informed consent document since the last review	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.	Were these protocol/Informed Consent Document (ICD) amendments approved by the YEC 2	Yes <input type="checkbox"/> No <input type="checkbox"/>
11.	If no, mention the amendments not approved	(Attach separate sheet)
12.	Which protocol amendment is the site following at present?	
13.	Which Informed consent amendment is the site following at present?	
14.	Has any information appeared in the literature, or evolved from this or similar research that might affect the YEC 2/YEC 2's evaluation of the risk/benefit analysis of participants involved in the protocol?	
15.	Whether reports of SAEs so far have been reviewed by the YEC 2	

16.	Have any participating investigators been added or with drawn since last review	
17.	Is report of interim data analysis available?	
18.	Is report of the data safety and monitoring board available?	
19.	Have any investigators developed equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?	
	Signature of the PI with Date:	

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Decision for review process

<p>Assessment of Continuing Review Report by the YEC 2:</p> <ul style="list-style-type: none"> ▪ Chairperson /Member-Secretary only and informed to the YEC 2 members at meeting ▪ Any 2 YEC 2 members and informed to the YEC 2 members at meeting <p>Name of the YEC 2 members:</p> <p>1. _____</p> <p>2. _____</p>
<p>Signature with date: Chairperson/ Member-Secretary</p>

Note:

(Download the form, type the details, print, sign, scan and send to YEC2at yec2@yenepoya.edu.in. Please do not delete any of the text typed in the form)