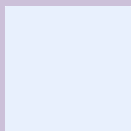


## (Annexure 3)

### Continuing Review/ Annual report format



(Logo of the institute)

(Name of the institute)

EC Ref. No. (for office use) \_\_\_\_\_

**\*The annual report must be duly submitted no later than 30 days before the annual year's completion.**

Title of study:

Principal Investigator (Name, Designation and Affiliation)

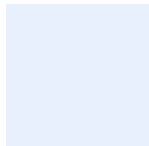
1.	EC Reference No.:		
2.	Date of EC Approval: <small>Click here to enter a date.</small>	Duration of Approval <span style="float: right;">months/ years</span>	
3.	Date of Start of study: <small>Click here to enter a date.</small>	Proposed date of Completion: <small>Click here to enter a date.</small>	
	Period of Continuing Report <small>Click here to enter a date.</small>	To <small>Click here to enter a date.</small>	
4.	<p>Does the study involve recruitment of participants? <span style="float: right;">Yes <input type="checkbox"/> No <input type="checkbox"/></span></p> <p>(a) If yes, Total number expected      No. Screened:      No. Enrolled:</p> <p style="margin-left: 40px;">Number Completed:      No. on followup:      .</p> <p>(b) Enrolment status – ongoing / completed/ stopped</p> <p>(c) Report of DSMB<sup>16</sup> <span style="float: right;">Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/></span></p> <p>(d) Any other remark</p>		
	<p>(e) Have any participants withdrawn from this study since the last approval? <span style="float: right;">Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/></span></p> <p style="margin-left: 40px;">If yes, total number withdrawn and reasons:</p>		
5.	<p>Is the study likely to extend beyond the stated period<sup>17</sup>? <span style="float: right;">Yes <input type="checkbox"/> No <input type="checkbox"/></span></p> <p style="margin-left: 40px;">If yes, please provide reasons for the extension</p>		
6.	<p>Have there been any amendments in the research protocol/informed consent document (ICD) during the past approval period? <span style="float: right;">Yes <input type="checkbox"/> No <input type="checkbox"/></span></p> <p style="margin-left: 40px;"><b>If No, skip to item no.6</b></p>		
	<p>(a) If yes, date of approval for protocol and ICD : <small>Click here to enter a date.</small></p>		
	<p>(b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? <span style="float: right;">Yes <input type="checkbox"/> No <input type="checkbox"/></span></p> <p style="margin-left: 40px;">If yes, when / how:</p>		

<sup>16</sup>In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.

<sup>17</sup>Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC

7. Is any new information available that changes the benefit -risk analysis of human participants involved in this study? Yes ☐ No ☐  
If yes, discuss in detail:
8. Have any ethical concerns occurred during this period? Yes ☐ No ☐  
If yes, give details
9. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐  
  
Describe in brief:  
(b) Have any SAE's occurred since last review? Yes ☐ No ☐  
If yes, number of SAE's :            Type of SAE's:  
(c) Is the SAE related to the study? Yes ☐ No ☐  
Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐
10. Has there been any protocol deviations/violations that occurred during this period? If yes, number of deviations  
Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐
11. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC  
Yes ☐ No ☐ NA ☐
12. Are there any publications or presentations during this period? If yes give details Yes ☐ No ☐
13. Brief Summary of the Study (up to 500 words) (to briefly describe the status, findings, activities undertaken, any deviations or changes, special mentions etc.)

Signature of PI:



[Click here to enter a date.](#)