

SAE Report Checklist
INSTITUTIONAL ETHICS COMMITTEE
HM PATEL CENTRE FOR MEDICAL CARE AND EDUCATION, KARAMSAD

Check list for SAE Reporting

Sr. No.	Heading	Yes	No
1	Details of examination of events by Ethics Committee		
2	Minutes of SAE Sub-Committee Meeting		
3	Due analysis report of the SAE		
4	Details of documents perused		
5	Causality Assessment as per WHO/ Naranjo Criteria		
6	Justification with documentary evidence with regards to relation/ no relation of the SAE as per Rule 122 DAB and Appendix XII of Schedule Y, Drugs and Cosmetics Rules		
7	Risk Factor Assessment in case of SAE - Death		
8	Calculation of compensation as per CDSCO formula – B x F x R/ 99.37 in SAE - Death		
9	Calculation of compensation as per CDSCO formula in SAE – Other than death [as applicable group]		
10	Opinion and Recommendation of the SAE Sub-Committee		
11	Attachments:		
	a. Copy of initial intimation report with Appendix XI		
	b. Copy of last intimation report with Appendix XI		
	c. Copy of minutes of meeting [SAE Sub-Committee]		
	d. Copy of 'cause of death certificate' [if applicable and available]		
	e. Causality Assessment Form [with signatures of all members and approval by Chairman]		
	f. Copy of documentary evidence of the relation of SAE with trial molecule		

Project Title:

Reference:

- Protocol Number:
- Centre Number:
- Patient ID:
- SAE:
- Date: