INSTITUTIONAL ETHICS COMMITTEE
H. M. PATEL CENTRE FOR MEDICAL CARE & EDUCATION
KARAMSAD, GUJARAT -388325
[Reg. No. ECR/ 331/ Inst/ GJ/ 2013/ RR-16]

CHECKLIST FOR REVIEW OF SUBMITTED SERIOUS ADVERSE EVENT (SAE)

Name of reviewer	
Designation in IEC	
Date of SAE Review Meeting	
Protocol ID	
Date of receipt of SAE	
Principal Investigator	

Serial No.	Details	Observation
1.	Copy of Clinical Trial permission obtained from CDSCO	Available/ Not available
2.	CTRI Registration No.	Available/ Not available
3.	Sponsor(Address with contact no and Email)	Available/ Not available
4.	Initial / Follow-up (FU)	Available/ Not available
5.	**Patient Details**	
	Initials & other relevant identifier (hospital/OPD record number etc.)	Available/ Not available
	Age & Gender	Available/ Not available
	Address	Available/ Not available
6.	**Details of drug**	
	*Suspected Drug(s)	Available/ Not available
	*Generic name of the drug	Available/ Not available
	*Indication(s) for which suspect drug was prescribed or tested	Available/ Not available
	*Dosage form and strength	Available/ Not available
	*Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)	Available/ Not available
	*Route of administration	Available/ Not available
	*Starting date and time of day g) Stopping date and time, or duration of treatment	Available/ Not available
	*Other Treatment(s): (including nonprescription/ OTC Drugs) and nondrug therapies, as for the suspected drug(s)	Available/ Not available
7.	*Details of the events: Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious	Available/ Not available

	Date (and time) of onset of reaction Stop date (and time) or duration of reaction	Available/ Not available
8.	*De-challenge and re-challenge information	Available/ Not available/ NA
9.	**Setting (e.g., hospital, out-patient clinic, home, nursing home)	
10.	**Outcome**	
	**Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.	Available/ Not available
	**For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.	Available/ Not available/ NA
	- Laboratory investigations report /Discharge summary (if available and applicable)	Available/ Not available
	- Post-mortem report (if applicable)/ Any additional documents)	Available/ Not available/ NA
11.	**Causality Assessment (Related/ Unrelated) by Investigator	Done/ Not done
12.	**Causality Assessment (Related/ Unrelated) by sponsor	Received/ Not received
13.	*Details about the Investigator	Available/ Available
14.	*Duly filled SAE Form as per Appendix XI of Schedule Y	Yes/ No
15.	****Has the participant made a claim?	Yes/ No
16.	ADDITIONAL DOCUMENTS REQUIRED FROM INVESTIGATOR (if any):	
17.	Other comments [if any]:	

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18	**At SAE Review Meeting**	
	*What is the investigator's assessment for causality	Related/ Not related
	***Basic Scientist assessment based on IB [latest version]	
	****Details of payment for medical management of SAE? (please give information who paid how much was paid, to whom, with evidence of the same)	
	Recommendations:	

Mandatory for:
*Clinician
**Lay person, Social Scientist
***Basic Scientist
****Legal Expert

Signature with date