INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital





IEC-I Re-registration No. ECR/229/Inst./MH/2013/RR-16,IEC-II registration No. ECR/417/Inst./MH/2013 Issued under rule 122DD of Drugs & Cosmetic rule 1945.

Recognized by:

The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER),
Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP)
for its compliance with international and local standards in ethical review.

Annexure 1

AX 01/SOP 11-B/V5

Checklist for Serious Adverse Event & Unexpected Serious Adverse Event submission

Sr. No.	Details			
1.	Country (Name of the country should be specified)			
2.	SAE report of death or other than death, Please tick (✓)	Deat	:h	Other than Death
		Yes	/ No	Page No.
3.	In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant (Please specify Yes/No) in the box			5
4.	Protocol Title			
5.	Protocol Study No./ ID /Code			
6.	Copy of Clinical Trial permission obtained from CDSCO			
7.	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)			
8.	Sponsor(Address with contact no and Email)			
9.	CRO (Address with contact no and Email)			
10.	Initial / Follow-up (FU)			
11.	In case of follow-up: Date & Diary no of initial or			
	recently submitted report information			
12.	Patient Details			
a)	Initials & other relevant identifier (hospital/OPD			
	record number etc.)			
b)	Gender			
c)	Age and/or date of birth			
<u>d)</u>	Weight			
e)	Height			
13.	Suspected Drug(s)			
<u>a)</u>	Generic name of the drug.			
b)	Indication(s) for which suspect drug was prescribed or tested.			
c)	Dosage form and strength.			
<u> </u>	Daily dose and regimen (specify units - e.g., mg, ml,			
	mg/kg).			

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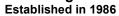
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f) Starting date and time of day. g) Stopping date and time, or duration of treatment 14. Other Treatment(s)	
g) Stopping date and time, or duration of treatment 14. Other Treatment(s)	
14. Other Treatment(s)	
Provide the same information for concomitant drugs	
(including non prescription/OTC Drugs) and non-drug	
therapies, as for the suspected drug(s).	
15. Details of the events	
a) Full description of event (s) including body site and	
severity, as well as the criterion (or criteria) for	
regarding the report as serious. In addition to a	
description of the reported signs and symptoms,	
whenever possible, describe a specific diagnosis for	
the reaction.	
b) Start date (and time) of onset of reaction.	
c) Stop date (and time) or duration of reaction.	
d) Dechallenge and rechallenge information.	
e) Setting (e.g., hospital, out-patient clinic, home, nursing	
home).	
16. Outcome	
a) Information on recovery and any sequelae; results of	
specific tests and/or treatment that may have been	
conducted.	
b) For a fatal outcome, cause of death and a comment on	
its possible relationship to the suspected reaction; any	
post-mortem findings.	
c) Other information: anything relevant to facilitate assessment of the case, such as medical history	
including allergy, drug or alcohol abuse; family history;	
findings from special investigations etc.	
17. Details about the Investigator	
a) CT Site Number, if any	
b) Name	
c) Address	
d) Telephone/Mobile Number & Email	
e) Profession (speciality)	
f) Date of reporting the event to Licensing Authority:	
g) Date of reporting the event to Ethics Committee	
overseeing the site:	

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h)	Signature of the Investigator	
18.	Details about the Ethics Committee	
a)	Name & Address	
b)	Name of Chairman & Address	
c)	Telephone/Mobile Number	
d)	Email	
19.	Adverse Event Term / Details of SAE	
20.	Causality Assessment (Related/Unrelated) by	
	Investigator.	
21.	Causality Assessment (Related/Unrelated) by	
	Sponsor/CRO	
22.	Details of compensation provided for injury or death.	
	In case no compensation has been paid, reason for the	
	same :	
23. a)	Duly filled SAE Form as per Appendix XI of Schedule Y	
b)	Laboratory investigations report /Discharge summary	
	(if available and applicable)	
c)	Post-mortem report (if applicable)/ Any additional	
	documents)	

Note: Information not relevant to a particular SAE should be marked with NA