



## INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth G. S. Medical College and KEM Hospital, Mumbai.

IEC No. of the Project: \_\_\_\_\_

### Annexure 3

AX 03/SOP11-B/V7.1

### **Serious Adverse Event Close out Report** **(For SAE at the site)**

Sr. No.	Details	
1.	EC Project No. & Title	
2.	SAE term:	
3.	Date of onset:	
4.	Initial reporting date to IEC	
5.	Follow up reporting date to IEC:	
6.	Causality assessment of SAE by	Related / Not related
	a. Principal Investigator	
	b. IEC	
	c. Sponsor	
	If related compensation recommended by IEC:	
7.	Medical care expenses paid by PI/ participants.	
8.	Reimbursement by PI if SAE is related: Yes/ No. Proofs provided - Yes/No.	
9.	SAE narrative in short	
10.	Event resolved- participant recovered / temporarily disabled/permanently disabled/ Death	
11.	Compensation paid or not paid	



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12.	SAE Close out details	
13.	Procedures completed – Yes /No, if not completed what are the reasons?	

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date