

Annexure 3 AX 03/SOP 11-B/V6.1



Serious Adverse Event close out Report (For SAE at the site)

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No.

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

For IEC office use only

Verified by:

Name: _____

(Signature with date of IEC administrative staff) _____

Signature of Principal Investigator: _____ Date _____