



INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital

Established in 1986

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.

Annexure1

AX 01/SOP 10/V5

Deviation / Non-Compliance / Violation Record

IEC Protocol no.:	
Study Title:	
Principal Investigator:	
Department:	
<input type="checkbox"/> Deviation from protocol	<input type="checkbox"/> Violation
Description of deviation (s)/violation(s) [If protocol deviations / violations are more than one please give the information in following tabular form:	
Reported by (Name of Principal Investigator):	
Signature with date: _____	

Sr. No	Patient initials &	Protocol deviation	impact of the deviation		Corrective measures by PI
	Patient ID.		Safety wellbeing of the participants	Data integrity	
1.					
2.					