



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.*

Annexure 1

AX 01/SOP 06/V5

Protocol / Protocol related documents Amendment Request and Assessment Form

IEC Protocol Number:	
Protocol Title: 	
Principal Investigator and Department: 	
Approved date:	No. of amendment:
<input type="radio"/> State/describe the amendment :type of document/ part of document amended 	
<input type="radio"/> Reasons for the amendment 	
<input type="radio"/> Impact of your amendment on your present study at this site: (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other) 	
Have the changes modifications in the amended versions been highlighted/ underlined? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Name of Principal Investigator: _____	
Signature with Date: _____	