

# 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 2

AX 02/SOP 07/V5

### **Continuing Review Application Form**

Date: \_\_\_\_\_

<b>Protocol No.:</b>	<b>Date of IEC approval:</b>
<b>Protocol Title:</b>	
<b>Principal Investigator :</b>	
<b>Department :</b>	
<b>Summary of protocol participants:</b> _____ No. of participants approved by IEC _____ No. of recruited participants _____ No. of ongoing participants _____ No. of Completed participants _____ No. of participants who refused to consent  <b>Have any participants been withdrawn from this study?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes (state the number and reasons for drop-outs of each participant, attach separate sheet if needed) _____ _____ <b>Impaired participants</b> <input type="checkbox"/> None <input type="checkbox"/> Physically <input type="checkbox"/> Cognitively <input type="checkbox"/> Both	<b>Has any information appeared in the literature, or evolved from this or similar research that might affect the IEC/IEC's evaluation of the risk/benefit analysis of participants involved in this protocol?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes (attach separate sheet if needed) _____ <b>Have any unexpected complications or SAEs been noted since last review at our site?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes (attach separate sheet if needed) <input type="checkbox"/> No. of patients who had SAEs- _____ <input type="checkbox"/> Whether reports of SAEs at have been submitted to the IEC- _____ <input type="checkbox"/> Whether reports of SAEs at other sites have been submitted to the IEC- _____ <input type="checkbox"/> Types of adverse events with nos. of participants- _____ _____ _____

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<p><b>Have there been any amendments in protocol/ Informed Consent Document since the last review?</b></p> <p><input type="checkbox"/> NO</p> <p><input type="checkbox"/> YES</p> <p><b>Were these protocol/ Informed Consent Document (ICD) amendments approved by IEC?</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes</p> <p>If no, mention the amendments not approved</p> <hr/> <hr/> <p>—</p> <p><b>Which protocol amendment is the site following at this date</b></p> <hr/> <p><b>Which ICD amendment is the site following at this date</b></p> <hr/>	<p>—</p> <p><input type="checkbox"/> Number of unexpected AE</p> <hr/> <p><b>Have any participating investigators been added or withdrawn since last review?</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes (Identify all changes in the attached narrative)</p> <p><b>Is report of interim data analysis available?</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes (submit as an attachment)</p> <p><b>Is report of the data safety and monitoring board available?</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes (submit as an attachment)</p> <p><b>Have any investigators developed equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes (Append a statement of disclosure)</p>
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**Signature of the Principal Investigator with Date:**

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