



**INSTITUTIONAL ETHICS COMMITTEE (IEC)-II**  
**Relating to Biomedical and Health Research (BHR).**  
**Seth GS Medical College and KEM Hospital, Mumbai, Maharashtra, India.**  
**Established - 14<sup>th</sup> November 2008**

**Recognized by:** SIDCER & FERCAP: 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, Awarded on Nov 20, 2016

**Registered by:** Govt of India, Ministry of Health & Family Welfare, Dept of Health Research (DHR), Registration No. EC/NEW/INST/2021/MH/0002 Valid from 22<sup>nd</sup> October 2021 to 21<sup>st</sup> October 2026.


Dear Investigators,


You are requested to submit the following **Mandatory Documents** in a cardboard file and in a pen drive (will return to you) to IEC for review and approval. Without following mandatory documents admin will not be able to accept the proposal **by order**. Hence, you are requested to kindly Co-operate with IEC administrative staff and submit your proposal in standard format.

<b>Thesis / Dissertation, Other Academic and GOVT sponsored studies:</b>	
1	Administrative sanction for a) conducting the study. b) sending samples outside KEMH (if applicable) (Mandatory for govt sponsored studies and collaborative studies)
2	Covering letter by PI for Initial submission of protocol review (available on <a href="http://www.kem.edu">www.kem.edu</a> )
3	DRB approval (please submit the IEC approval letter to DRB within 6 months of DRB and if delayed please submit the reason to the chairperson of DRB for further course of action and submit copy for the same to IEC. Investigators cannot sign the DRB as Chairperson).
4	<b>All required Annexures</b> As per SOPs, Duly signed scanned PDF versions (not photographs) for soft copies, must be readable on pen drive (pen drive will be returned to you) + Original signed hard copies. Vulnerable group annexures if applicable Waiver of consent annexure if applicable
5	Protocol (Power Point document not acceptable)
6	ICDs – English, Hindi & Marathi mandatory
7	CRF Questionnaire (English, Hindi & Marathi if applicable) Scales (English, Hindi & Marathi if applicable)
8	Draft MOU (for govt sponsored studies and collaborative studies)
9	Minimum 15 References which are cited in text in Vancouver style (for dissertation / thesis)
10	CV, valid MMC (medical personnel) of all team members
11	Valid GCP of all team members

**All documents should be readable in PDF format.**

Thanking you,

  
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