



# INSTITUTIONAL ETHICS COMMITTEE (IEC)-I

for Clinical Trial, Bioavailability and Bioequivalence Study and  
Relating to Biomedical and Health Research (BHR).

Seth GS Medical College and KEM Hospital, Mumbai, Maharashtra, India.

Established - 6<sup>th</sup> January 1987

SOP original  
file

**Registered by:** Govt of India, DGHS, CDSCO DCGI & Licensing Authority: Drugs Controller General (India),  
Re-Registration No. ECR/229/Inst./MH/2013/RR-19 Valid from 22.04.2019 to 21.04.2024 &  
Govt of India, Ministry of Health & Family Welfare, Dept of Health Research (DHR), Registration No. EC/NEW/INST/2021/MH/0008  
Valid From 22<sup>nd</sup> October 2021 to 21<sup>st</sup> October 2026.

**Accredited by:** NABH: National Accreditation Board for Hospitals & Healthcare Providers (Constituent Board of Quality Council of India)  
Valid from May 19, 2021 thru May 18, 2024 Certificate No. EC-CT-2018-0027

5<sup>th</sup> July 2024

Dear investigators,

As you are aware, the validity of Institutional Ethics Committee (IEC) Standard Operating Procedures (SOPs) version 6.1 is over on 31<sup>st</sup> July 2023. In regard to SOP revision, the IEC has issued SOP addendum 1, 2, 3, 4 & 5 which are available on [www.kem.edu](http://www.kem.edu) website. The NABH accreditation program of IEC-I is scheduled in the third quarter of the year 2024. Subsequently we will receive recommendations from NABH auditors for the SOPs. We will incorporate these suggestions and the addendum in the new SOPs version 7.

Meanwhile, please follow the following SOPs version 6.1 and other applicable SOPs/ addendum pertaining to the SOP 6.1 for the management of all research projects/clinical trials.

### List of SOPs and SOP addendum of Institutional Ethics Committee, KEMH, Mumbai.

| No.     | Title of the Standard Operating Procedures (SOPs)  | SOP Code       | Page No.   |
|---------|--|----------------|------------|
| 1.      | Preparation of Standard Operating Procedures (SOPs) for Institutional Ethics Committee (IEC)                                 | SOP 01/V6.1.1  | 1 of 239   |
| 2.      | Constituting Institutional Ethics Committee  | SOP 02/V6.1    | 8 of 239   |
| 3.      | Confidentiality / Conflict of Interest Agreements  | SOP 03/V6.1    | 26 of 239  |
| 4.      | Selection and Responsibilities of Subject Expert   | SOP 04/V6.1    | 36 of 239  |
| 5.      | Management of Initial Protocol Submissions   | SOP 05/V6.1    | 41 of 239  |
| 5-A     | Full Board Review of Submitted Protocol  | SOP 05-A/ V6.1 | 82 of 239  |
| 5-B     | Expedited Review   | SOP 05-B/ V6.1 | 99 of 239  |
| 5-C     | Exemption from the Ethics Review for Research Projects   | SOP 05-C/ V6.1 | 107 of 239 |
| 5-D     | Review of Resubmitted Protocols  | SOP 05-D/ V6.1 | 113 of 239 |
| 6.      | Review of Amended protocol/ Protocol related documents   | SOP 06/V6.1    | 116 of 239 |
| 7.      | Continuing Review of Study Protocols   | SOP 07/V6.1    | 123 of 239 |
| 8.      | Review of Study Completion Reports   | SOP 08/V6.1    | 130 of 239 |
| 9.      | Management of Premature Termination / Suspension / Discontinuation of the study / Withdrawal of study before site initiation | SOP 09/V6.1    | 136 of 239 |
| 10.     | Protocol Deviation/Violation   | SOP 10/V6.1    | 140 of 239 |
| 11. (A) | Constituting SAE Subcommittee  | SOP 11-A/ V6.1 | 146 of 239 |
| 11. (B) | Review of Serious Adverse Events (SAE) Reports and Unexpected Adverse Events (UAE)   | SOP 11-B/ V6.1 | 152 of 239 |
| 12.     | Site Monitoring Visit  | SOP 12/V6.1    | 163 of 239 |
| 13.     | Agenda Preparation, Meeting Procedures and Recording of Minutes  | SOP 13/V6.1    | 176 of 239 |
| 14.     | Conduct of Emergency Meeting   | SOP 14/V6.1    | 188 of 239 |
| 15.     | Maintenance of Active Project Files  | SOP 15/V6.1    | 191 of 239 |
| 16.     | Archiving and Retrieving Documents   | SOP 16/V6.1    | 194 of 239 |
| 17.     | Responding to Research Participant's Request or Complaint  | SOP 17/V6.1    | 198 of 239 |
| 18.     | Management of complaints by investigators  | SOP 18/V6.1    | 202 of 239 |

u  
5/7/24

Page 1/2



# INSTITUTIONAL ETHICS COMMITTEE (IEC)-I

for Clinical Trial, Bioavailability and Bioequivalence Study and  
Relating to Biomedical and Health Research (BHR).

Seth GS Medical College and KEM Hospital, Mumbai, Maharashtra, India.

Established - 6<sup>th</sup> January 1987

**Registered by:** Govt of India, DGHS, CDSCO DCGI & Licensing Authority: Drugs Controller General (India),  
Re-Registration No. ECR/229/Inst./MH/2013/RR-19 Valid from 22.04.2019 to 21.04.2024 &  
Govt of India, Ministry of Health & Family Welfare, Dept of Health Research (DHR), Registration No. EC/NEW/INST/2021/MH/0008  
Valid From 22<sup>nd</sup> October 2021 to 21<sup>st</sup> October 2026.

**Accredited by:** NABH: National Accreditation Board for Hospitals & Healthcare Providers (Constituent Board of Quality Council of India)  
Valid from May 19, 2021 thru May 18, 2024 Certificate No. EC-CT- 2018-0027

|     |   |             |            |
|-----|---|-------------|------------|
| 19. | Request for Waiver of Written Informed Consent  | SOP 19/V6.1 | 209 of 239 |
| 20. | Reviewing proposals involving vulnerable Populations.                                     | SOP 20/V6.1 | 211 of 239 |
| 21. | Common Ethic Review of Multicentre Research   | SOP 21/V6.1 | 229 of 239 |
| 22. | Management of initial protocol submission during epidemics/ pandemics<br>lockdown periods | SOP 22/V 1  | 236 of 239 |
| 23. | Emergency or compassionate use of drugs   | SOP 23/V1   | 1 to 3     |
| 24. | Review of Case Reports and Case Series  | SOP 24/V1   | 1 to 3     |
| 25. | Audio Visual (AV) Recording of Informed Consent Process                                   | SOP 25/V1   | 1 to 8     |
|     |   |             |            |
| 1.  | SOP Addendum 1 dated 21 <sup>st</sup> May 2021  | Addendum 1  | 1 to 9     |
| 2.  | SOP Addendum 2 dated 27 <sup>th</sup> December 2022                                       | Addendum 2  | 1 to 3     |
| 3.  | SOP Addendum 3 dated 3 <sup>rd</sup> May 2023   | Addendum 3  | 1 to 22    |
| 4.  | SOP Addendum 4 dated 1 <sup>st</sup> Nov 2023   | Addendum 4  | 1 of 1     |
| 5.  | SOP Addendum 5 dated 20 <sup>th</sup> March 2024  | Addendum 5  | 1 to 2     |

*5th July '24*  
Dr. Nithya Gogtay  
Jt. Member Secretary, IEC-I

*5/7/24*  
Dr. Raakhi Tripathi  
Member Secretary, IEC-I

**Dr. NITHYA GOGTAY**  
Jt. Member Secretary  
IEC-I

**DR. RAAKHI TRIPATHI**  
Member Secretary  
IEC-I

*5/17/24*  
Dr. Sangeeta Ravat  
Dean, Seth GSMC & KEMH  
Parel, Mumbai.

Dean, K.E.M.H. & Seth G.S.M.C.,  
Parel, Mumbai - 400 012.

