

Annual report as on 20th December 2019
INSTITUTIONAL ETHICS COMMITTEE (IEC) I, II & III

Registration / Accreditation / Recognition	IEC-I	IEC-II	IEC-III
Established on	6 th January, 1987	14 th November, 2008	12 th October, 2019
Registration with: DCG(I) & Central Licensing Authority: (issued under New Drugs and Clinical Trials Rules, 2019.)	Re-Registration No. ECR/229/Inst./MH/2013/RR-19	Re-Registration No. ECR/417/Inst./MH/2013/RR-19	NA
	Valid from 22.04.2019 to 21.04.2024	Valid from 06.08.2019 to 05.08.2024	NA
Provisional registration of the Ethics Committee under Dept of Health Research (DHR), Ministry of Health & Family Welfare, Delhi.	Registration provisionally approved on 12-OCT-2019	Registration provisionally approved on 12-OCT-2019	Registration provisionally approved on 12-OCT-2019
Recognition: SIDCER & FERCAP: Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Forum for Ethical committees in Asia and the Western Pacific Region (FERCAP) for its compliance with international and local standards in ethical review.	Valid from Nov 20, 2016 thru Nov 19, 2020	Valid from Nov 20, 2016 thru Nov 19, 2020	NO
Accreditation: NABH: National Accreditation Board for Hospitals & Healthcare Providers (Constituent Board of Quality Council of India).	Valid from May 19, 2018 thru May 18, 2021 Certificate No. EC-CT- 2018-0027	Valid from October 30, 2018 thru October 29, 2021 Certificate No. EC-CT- 2018-0057	NA
Current SOPs Version 6, Dated 2 nd April 2018 effective from 1 st July 2018			
Institutional Ethics Committees presently functions according to the requirements laid down in New Drugs and Clinical Trials Rules, 2019 and is guided by the ICH GCP guidelines for Good Clinical Practice, ethical principles set forth in the Declaration of Helsinki and the Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research.			

Activities of the IECs

1. No. of full board & SAE Subcommittee meetings held in the year 2019

Year 2019	IEC-I	IEC-II	IEC-III	SAE Subcommittee	Total meetings
	11	12	2	28	53 meetings

2. No. of projects reviewed by IECs (I, II & III) in the year 2019

Year 2019	PHARMA sponsored	GOVT sponsored	Other Academic	Thesis / Dissertations	Total Total projects
till 20 th Dec 2019	20	8	147	175	350

3. No. of ongoing projects with IECs in the year 2019

Year 2019	IEC-I	IEC-II	IEC-III	TOTAL
PHARMA sponsored	39	-	-	39
GOVT sponsored	-	10	13	23
Other academic	3	145	122	270
Thesis / Dissertation	4	275	272	551
TOTAL				883

4. No. of Serious Adverse Events (SAEs) occurred in the year 2019

Total 30 SAE meeting held till 20 th December 2019						
	Particulars		PHARMA	GOVT	OA	THESIS
1	Total no. of SAE at our site:	Initial report	08	-	-	-
		Follow up report	13	-	-	-
		causality	-	-	-	-
2	Total no. of death		01	-	-	-
3	Our site late reporting (after 24 hours)		-	-	-	-

4	Responses (query) from EC regarding our site SAEs	Query letters sent	16	-	-	-
		Noted letters sent	22	-	-	-
7	Total no. of Adverse Events (AE) reported		33	-	-	-
8	Total no. of SUSAR/CIOMS reported:		21699	-	-	-

Constitution of IEC-I

Sr. No.	Name	Position on (IEC)-I	Affiliation	Designation	Qualification	Gender
1.	Dr. Padmavathy Menon	Chairperson	Non-Affiliated	Consultant Endocrinologist, Jupiter Hospital, Thane & LH Hiranandani Hospital, Powai, Mumbai.	M.D.	F
2.	Dr. Sandeep Bavdekar	Co-Chairperson & Clinician	Non-Affiliated	Pediatrician	M.D., D.N.B., D.C.H., F.C.P.S., F.M.E.	M
3.	Dr. Shruti Bhide	Member Secretary	Affiliated	Associate Professor (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F
4.	Dr. Yashashri Shetty	Member (Joint Member Secretary)	Affiliated	Associate Professor (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai.	MD, DBM.	F
5.	Dr. Urmila Thatte	Member (Basic medical scientist)	Affiliated	Professor & Head (Clinical Pharmacology) Seth GS Medical College and KEM Hospital Mumbai.	M.D., DNB., Ph.D.	F
6.	Dr. Vishal Gupta	Member (Clinician)	Affiliated	Assistant Professor (Medicine) Seth GS Medical College and KEM Hospital Mumbai.	MD	M
7.	Ms. Meera Shah	Member (Social Scientist)	Non-Affiliated	-	M.A. Clinical Psychology M.S.W	F

					Diploma in Journalism	
8.	Ms. Veena Johari	Member (Legal expert)	Non-Affiliated	Independent Lawyer	L.L.B.	F
9.	Dr. Sai Kulkarni	Member (Lay person)	Non-Affiliated	-	B.A., D.C.A., PGDEM, M.E.M./PhD, M.A	F
10.	Dr. SanjeevaniZadkar	Member (Clinician)	Affiliated	Associate Professor (Anaesthesia) Seth GS Medical College and KEM Hospital	MBBS,MD	F
11.	Dr. Kaizad Damania	Member (Clinician)	Non-Affiliated	Professor (Obstetrics &Gynaecology) N. Wadia Maternity Hospital, Mumbai.	M. D., DNB., F.C.P.S., D.G.O., D.F.P.	M
12.	Dr. Ragini Kulkarni	Member (Clinician)	Non-Affiliated	Scientist Department: Department of Operational Research (DOR)National Institute for Research in Reproductive Health JehangirMerwanji Street, Parel, Mumbai 400012	M.D. (Preventive and Social Medicine, 1997)	F

Constitution of IEC-II

Sr. No.	Name	Position on IEC-I	Affiliation	Designation	Qualification	Gender
1.	Dr. Subodh Sirur	Chairperson (External)	Non-Affiliated	WockhardtHospital, Mumbai Central, Mumbai	MBBS, DVD, LLM Consultant, Dermatology & Venerology,	M
2.	Dr. AlkaSubramaniyam	Co-Chairperson (External) (Clinician)	Non-Affiliated	Associate Professor (Psychiatry) TNMC & BYL Nair Charitable Hospital, Mumbai.	M.D., D.N.B., DHA.	F
3.	Mrs. PalsuleShilpshree	Member Secretary	Affiliated	Assistant Professor (occupational Therapy) Seth GS Medical College and KEM Hospital Mumbai. Mumbai.	M.Sc OT	F

4.	Dr. Sharmila Jalgaonkar	Joint- Member Secretary (Basic medical scientist)	Affiliated	Associate Professor (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F
5.	Dr. Swapna Kanade	Member	Affiliated	Associate Professor, (Microbiology) Seth GS Medical College and KEM Hospital Mumbai.	MD	F
6.	Dr. Smrati Bajpai	Member	Affiliated	Assistant Professor (Medicine) Seth GS Medical College and KEM Hospital Mumbai /	M.D., DNB	F
7.	Dr. Pradnya Talawdekar	Alternate Member (External legal Expert)	Non-Affiliated	Independent Lawyer/ Project Manager, Ojus Medical Institute, The Tulip Star, Juhu Tara Road Juhu, Mumbai.	B.A.M.S., L.L.M.	F
8.	Dr. Nilesh Thakre	Member (Social scientist)	Non-Affiliated			M
9.	Dr. Sai Kulkarni	Member (Lay person)	Non-Affiliated	-/-	B.A., D.C.A., PGDEM, M.E.M./ PhD, M.A	F
10.	Dr. Sona Dave	Member (External scientific expert) (Clinician)	Non-Affiliated	Professor, (Anaesthesiology) TNMC & BYL Nair Charitable Hospital, Mumbai.	M.D., DA., DNB	F
11.	Dr. Priyanka Honavar	Member (Clinician)	Affiliated	Assistant Professor (Obstetrics & Gynaecology) Seth GS Medical College and KEM Hospital Mumbai	DGO, DNB(O BGYN), FMAS	F
12.	Dr. Sandeep Sonone	Member	Affiliated	Associate Professor (Orthopaedics) Seth GS Medical College and KEM Hospital Mumbai.	MS, DNB.	M

Constitution of IEC-III

Sr. No.	Name	Position on IEC-I	Affiliation	Designation	Qualification	Gender
1.	Dr. Leena V Gangolli	Chairperson (External)	Non- Affiliated	Member of National Task Force for Palliative Care.	M.B.B.S., M.H.A. (T.I.S.S.),M.P. H.(Harvard University), L.L.M. (University of Mumbai)	F
2.	Dr. Sushma Save	Co-Chairperson (External)	Non- Affiliated	Associate Professor, Dept of Pediatrics, Topiwala National Medical College & B. Y. L. Nair Charitable Hospital.	MD,DCH, IBCLC (USA).	F
3.	Dr. AmeyRojekar	Member Secretary	Affiliated	Assistant Professor (Pathology) Seth GS Medical College and KEM Hospital Mumbai.	M.D., D.N.B.	M
4.	Dr. SnehalataGajbhiye	Joint- Member Secretary (Basic medical scientist)	Affiliated	Assistant Professor (Pharmacology & Therapeutics)Seth GS Medical College and KEM Hospital Mumbai.	M.D., FICS.	F
5.	Dr. Kavita Joshi	Member (Clinician)	Affiliated	Associate Professor of Medicine, Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F
6.	Dr. MelitaVaz	Member (External Social Scientist)	Non- Affiliated	-	PhD MSW MA	F
7.	Dr. Sai Kulkarni	Member (Lay person) External	Non- Affiliated	-	Ph.D., M.A,	F
8.	Mrs. JaimalaShetye	(Member)	Affiliated	Associate Professor (Physiotherapy) Seth GS Medical College and KEM Hospital Mumbai.	MPTth	F
9.	Dr. Kranti Kadam	Member (Clinician)	Affiliated	Additional Professor (Psychiatry) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F

10.	Dr. SuchinDhamnaskar	Member (Clinician)	Affiliated	Associate Professor, Dept. of General Surgery, Seth GS Medical College and KEM Hospital Mumbai.	M.S	M
11.	Dr. Vijaya M. Babre	Member	Non- Affiliated	Assistant Professor in Department of OBGY at K.J. Somaiya Medical College Sion Mumbai.	MBBS,DNB,FI COG,FCPS,DG O,DFP,DHA (Diploma of Hospital Administration)	F
12.	Dr. Nandini Dave	Member (Clinician)	Affiliated	Professor & Head (Pediatric Anesthesia) Seth GS Medical College and KEM Hospital Mumbai	M.D.	F
13.	Dr. Yuvaraj B. Chavan	Member	Affiliated	Professor (Additional) (PSM) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	M

IEC-I, II& III Office bearers

<u>Institutional Ethics Committee – I , II & III</u>		
Ms. Janhavi Katkar (nayanvkatkar@gmail.com) General Manager.		
<u>IEC-I & SAE Subcommittee</u>	Mrs. ManaliNaik, Deputy Manager	<u>iec-1@kem.edu</u>
	Ms. ShwetaSurve, Deputy Manager	
<u>IEC-II</u>	Ms. Manasi Lad, Sr. Executive Assistant	<u>iec-2@kem.edu</u>
	Ms.RasikaNikharange, Executive Assistant	
<u>IEC-III & SAE Subcommittee</u>	Ms. PrajaktaAuti, Deputy Manager	<u>iec-3@kem.edu</u>

<u>IEC-I, II, III & SAE Subcommittee</u>	Mr. MangeshKhochade Mr. ShivprasadPawar	
Direct line: 24122188, 24107515 Cell no.: 9326688937 Ext. no. 7515		

Activities of the IEC

1. Training programs organized by IEC:

- **Three Good Clinical Practice training conducted on 5th March 2019 , 28th March 2019 18th July 2019**
- **Schedule Y & ICMR 2017 training conducted on 5th March 2019 , 28th March 2019 18th July 2019**
- **GSR 227 (E) training conducted on 11th April 2019, 3rd June 2019 & 18th July 2019**
- **SOP version 5.1 training conducted on 5th March 2019 & 28th March 2019**
- **SOP version 6 training conducted on 15th July 2019 & 18th July 2019**