

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital

Established in 1987

IEC-I Registered with DCGI, Re-Registration No. ECR/229/Inst./MH/2013/RR-16.
issued under Rule 122DD of the Drug & Cosmetic Rules 1945.

IEC-II Registered with DCGI, Re-Registration No. ECR/417/Inst./MH/2013/RR-16
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Recognized by:

*The 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*

Annual report as on 20th December 2018

INSTITUTIONAL ETHICS COMMITTEE (IEC) I & II

Established: 1987

Accreditation / Recognition	IEC-I	IEC-II
DCGI & Licensing Authority: Drugs Controller General (India)	Re-Registration No. ECR/229/Inst./MH/2013/R R-16	Re-Registration No. ECR/417/Inst./MH/2013/RR- 16
	Valid from 22.04.2016 to 21.04.2019	Valid from 06.08.2016 to 05.08.2019
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
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

Current SOPs Version 5.1, V5.1 Dated 2nd April 2018 effective from 1st July 2018

Both committees presently functions according to the requirements laid down in Schedule Y 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 IEC-I

A total of **41 meetings (12 full board meetings and 29 SAE Subcommittee meetings)** were held in the year 2018. A total of 22 pharmaceutical sponsored projects, 3 government sponsored project, 77 other academic projects and 134 thesis / dissertations were submitted to the IEC-I for initial review during the year.

3 other academic projects were approved at first submission as there were scientific and ethical lacunae in the submitted protocols. The comments by the IEC-I members, pertaining to modifications in the protocol were sent to investigators. The answers to IEC-I comments were then reviewed and the project was granted approval. Following is the status of the projects submitted to the IEC-I in the year 2018

Year 2018	Projects reviewed	Under Process	Approved
Pharmaceutical sponsored projects	20	9	11
GOVT sponsored projects	3	2	1
Thesis	123	40	83
Other Academic	77	33	44
Total	223	84	139

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In regards to sponsored studies:

		Year 2018	PHARMA	GOVT
I	Total no. of projects reviewed by IEC-I		20	3
III	Type of study	Phase I	-	1
		Phase II	2	-
		Phase III	11	-
		Phase IV	5	-
		Phase II & III	1	-
		BABE	-	-
		NA	1	-

Serious Adverse Events:

Total 29 SAE meeting held till 20 th December 2018						
Particulars		PHARMA	GOVT	OA	THESIS	
1	Total no. of SAE at our site:					
	Initial report	08	02	01	-	-
	Follow up report causality	12	02	01	-	-
2	Total no. of death	01	02	-	-	-
3	Our site late reporting (after 24 hours)	-	-	-	-	-
4	Responses (query) from EC regarding our site SAEs	Query letters sent	17	01	02	-
		Noted letters sent	24	03	01	-
7	Total no. of Adverse Events (AE) reported	-	-	-	-	-
8	Total no. of SUSAR/CIOMS reported:	3413	-	-	-	-

Status ongoing of the sponsored projects of IEC-I as on 20th December 2018

Year	Pharmaceutical sponsored projects	GOVT sponsored projects	Other Academic projects	Thesis	Total
2007	0	1	0	0	1
2012	1	1	0	0	2
2013	0	2	2	19	23
2014	2	2	4	18	26
2015	1	0	18	39	58
2016	3	4	33	64	104

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2017	5	1	45	98	149
2018	11	1	40	82	134
Total	23	12	142	320	497

Activities of the IEC-II in the year 2018

A total of 12 meetings were held in the year 2018. A total of 09 pharmaceutical sponsored projects, 05 government sponsored projects, 89 other academic projects and 129 thesis / dissertations were submitted to the IEC-II for initial review during the year.

1 thesis and 1 other academic projects was approved at first submission as there were scientific and ethical lacunae in the submitted protocols. The comments by the IEC-II members, pertaining to modifications in the protocol were sent to investigators. The answers to IEC-II comments were then reviewed and the project was granted approval. Following is the status of the projects submitted to the IEC-II in the year 2018

Year 2017	Total reviewed projects	Under Process	Approved
PHARMA	09	08	01
GOVT	05	03	02
Thesis	129	41	88
Other Academic	89	31	58
Total	232	83	149

Status of the ongoing academic projects as on 20th December 2018

Year	Pharmaceutical sponsored projects	GOVT sponsored projects	Other Academic projects	Thesis	Total
2009				1	1
2010			1		1
2011			1		1
2012			3		3
2013	2		2	52	56
2014		1	5	29	35
2015			11	34	45
2016	2	3	21	60	86
2017		3	28	101	132
Total	4	7	72	277	360

Total projects reviewed by the IEC-I & II in the year 2018

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	Departments	PHARMA	GOVT	Thesis	Other Academic
1.	Anaesthesia	-	-	39	17
2.	Anatomy	-	-	2	1
3.	Biochemistry	-	1	1	3
4.	Cardiology	3	-	-	-
5.	Clinical Pharmacology	1	-	-	6
6.	Chest Medicine	-	-	4	1
7.	Dermatology	2	-	7	4
8.	Dentistry	-	-	-	1
9.	Endocrinology	2	2	-	7
10.	ENT			4	-
11.	Forensic Medicine			1	6
12.	Gastroenterology	9		-	7
13.	General Surgery			24	5
14.	Hematology	2		-	-
15.	Medicine			29	3
16.	Microbiology			6	2
17.	Neurology	6		-	-
18.	Neonatology	1	1	-	6
19.	Nephrology			-	4
20.	Nuclear medicine			-	3
21.	Obstetrics and Gynaecology		-	26	5
22.	Orthopaedics	1		15	2
23.	Ophthalmology	1		2	-
24.	OT			9	3
25.	Pathology			16	1
26.	Paediatrics			17	1
27.	Paediatrics surgery			-	2
28.	Plastic Surgery			-	6
29.	Psychiatry		-	9	6
30.	PSM		3	18	18
31.	Pharmacology & Therapeutics	1		2	17

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32.	Physiology			2	3
33.	PT			7	17
34.	Radiology			8	-
35.	Surgical Gastroenterology			-	4
36.	Transfusion Medicine			4	-
37.	Urology		1	-	5
	TOTAL Reviewed	29	8	252	166

Constitution of IEC-I

Sr. No.	Name	Position on IEC-I	Designation & Affiliation	Qualification	Gender
1.	Dr. Padmavathy Menon	Chairperson (External)	Consultant Endocrinologist, Jupiter Hospital, Thane & LH Hiranandani Hospital, Powai, Mumbai.	M.D.	F
2.	Dr. Sharmila Jalgaonkar	Member Secretary	Associate Professor (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F
3.	Dr. Yashashri Shetty	Joint Member Secretary	Associate Professor (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai.	MD, DBM.	F
4.	Dr. Smrati Bajpai	Member (Physician)	Assistant Professor (Medicine) Seth GS Medical College and KEM Hospital Mumbai.	M.D., DNB.	F
5.	Dr. Urmila Thatte	Member (Basic medical scientist)	Professor & Head (Clinical Pharmacology) Seth GS Medical College and KEM Hospital Mumbai.	M.D., DNB., Ph.D.	F
6.	Ms. Veena Johari	Member (External Legal Expert)	Independent Lawyer	L.L.B.	F
7.	Dr. Uma Jadhav	Member (Social scientist)	Community Development Officer (Social Services) Seth GS Medical College and KEM Hospital Mumbai.	M.S.W., L.L.B, Ph.D (Health Systems Studies)	F
8.	Ms. Surinder V Mudaliar	Member	Office Superintendent Indian Railway.	M.A., B.Ed.	F

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Current Address: New UG/PG Hostel, 20 Storey Hostel Building, Ground Floor, KEM Hospital Campus, Near Main boys hostel, Dr. S.S. Rao Marg, Parel, Mumbai - 400012. Tel: +91 22 2412 2188 email: iec-1@kem.edu, iec-2@kem.edu

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		(Lay person)			
9.	Dr. Sandeep Bavdekar	Member (External scientific expert)	Pediatrician	M.D., D.N.B., D.C.H., F.C.P.S., F.M.E.	M
10.	Ms. Palsule Shilpshree	Member	Assistant Professor (occupational Therapy) Seth GS Medical College and KEM Hospital Mumbai. Mumbai.	MOTh	F
11.	Dr. Kaizad Damania	Member (External Scientific Expert)	Professor (Obstetrics &Gynaecology) N. Wadia Maternity Hospital, Mumbai.	M. D., DNB., F.C.P.S., D.G.O., D.F.P.	M
12.	Dr. Sona Dave	Member (External Scientific Expert)	Professor, (Anaesthesiology) TNMC & BYL Nair Charitable Hospital, Mumbai.	M.D., DA., DNB	F
13.	Dr. Alka A. Subramanyam	Member (External Scientific Expert)	Associate Professor (Psychiatry) TNMC & BYL Nair Charitable Hospital, Mumbai.	M.D., D.N.B., DHA.	F
14.	Dr. Amita Joshi	Member	Professor & Head (Pathology) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F
15.	Dr. Tushar Rathod	Member	Associate Professor (Orthopaedics) Seth GS Medical College and KEM Hospital Mumbai.	M.S., F.C.P.S., Ph.D(Ortho)	M

Constitution of IEC-II

	Name	Position on IEC-II	Designation & Affiliation	Qualification	Gender
1.	Dr. Alan F. Almeida	Chairperson	Consultant Nephrologist and Transplant Physician PD Hinduja Hospital, Mumbai.	MD., MNAMS (Nephrology).	M
2.	Dr. Snehalata Gajbhiye	Member Secretary	Assistant Professor (Pharmacology & Therapeutics)Seth GS Medical College and KEM Hospital Mumbai.	M.D., FICS.	F
3.	Dr. Amey Rojekar	Joint Member Secretary	Assistant Professor (Pathology) Seth GS Medical College and KEM Hospital Mumbai.	M.D., D.N.B.	M

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4.	Dr. Kavita Joshi	Member (Physician)	Associate Professor of Medicine, Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F
5.	Dr. Padmaja Marathe	Member (Basic medical scientist)	Professor (Additional) (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F
6.	Dr. Leena V. Gangolli	Member	Consultant, Palliative Care Consultant, Silver Innings Foundation.	M.B.B.S., M.H.A. (T.I.S.S.), M.P.H. (Harvard University), L.L.M. (University of Mumbai)	F
7.	Dr. Nilesh Thakre	Member (External Social Scientist)	Associate Professor, Psychology, SNDT Women's University, Mumbai.	Ph.D. Psychology, M.A (Industrial & Business Psychology), M.I.R.P.M., M.A. (Clinical Psychology), N.E.T in Psychology, PGDIP., Dip TD.	M
8.	Dr. Sai Kulkarni	Member (External Layperson)	-	PhD, M.A	F
9.	Dr. Yuvaraj B. Chavan	Member	Professor (Additional) (PSM) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	M
10.	Dr. Deepa Kane	Member	Professor (Anesthesiology) Seth GS Medical College and KEM Hospital Mumbai	M.D.	F
11.	Dr. Padmaja Samant	Member	Professor, (Obstetrics & Gynaecology) Seth GS Medical College and KEM Hospital Mumbai.	MBBS, M.D.	F
12.	Dr. Sunil Kuyare	Member	Associate Professor, (Microbiology) Seth GS Medical College and KEM Hospital Mumbai	M.D., PGDHA, FME.	M
13.	Dr. Sushma Save	Member ((External Scientific Expert))	Associate Professor, Dept of Pediatrics, Topiwala National Medical College & B. Y. L. Nair Charitable Hospital.	MD, DCH, IBCLC (USA).	F
14.	Ms. Jaimala Shetye	Member	Associate Professor (Physiotherapy) Seth GS	MPT	F

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			Medical College and KEM Hospital Mumbai.		
15.	Ms. VeenaJohari	Member (External Legal Expert)	Independent Lawyer	L.L.B.	F

IEC-I & II Office bearers

Mrs. JanhaviKatkar, Administrative Manager, (nayanvkatkar@gmail.com)

Mrs. ManaliNaik, Executive Assistant, IEC-I

Ms. Manasi Lad, Executive Assistant, IEC-I& SAE Subcommittee

Ms. ShwetaSurve, Executive Assistant, IEC-II

Ms. PrajaktaAuti, Executive Assistant, IEC-II &SAE Subcommittee

Ms.RasikaNikharange,Executive Assistant, IEC-I

Mr. MangeshKhochade, Office Attendant

Mr. Vijay Chavan, Office Attendant

Contact details: Email: iec-1@kem.edu, iec-2@kem.edu, Tel: 24122188, 24107515, Ext. no. 7515

Activities of the IEC

1. Training programs attended by IEC members and IEC staff:

2. Presented papers / poster related to research ethics at conference:

- 1) Presented paper in UK Sheth prize for oral prize category at 50 th Annual Conference of Indian Pharmacological Society organized by NMIMS Mumbai on 15-17 th February 2018 for the paper titled 'Audit of project proposals submitted to ethics committee to address the issue of vulnerability among research participants.
- 2) Paper presented at 18th FERCAP (Forum for Ethical Review Committees in the Asian and Western Pacific Region) International Conference at Chang Gung Memorial Hospital, Taoyuan, Taiwan during 19-20th November 2018.
Dr. Gajbhiye SV, Dr. Jalgaonkar SV, Ms Shweta Surve, MsManasi Lad. An observational study to assess completion reports for compliance of research proposals to the institutional ethics committee approved protocol.
- 3) Marathe PA*, Tripathi RK*, Kamat SK*, Shetty YC*, Kuyare SS**, Thatte UM***. Compensation for Participation in Research: A Review of Protocols and Informed Consent Documents Submitted for Review to two Ethics Committees. Perspectives in Clinical Research . 2018 April;9(2) : 64-9
- 4) ShettyYC , Singh VK, Brahma S and Saiyed A. Conflict Of Interest In Research And Its Current Status In India. World Journal Of Pharmacy And Pharmaceutical Sciences .2018 Oct 1 ;7(10): 805-816 ISSN 2278 – 4357

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3. Publication related to research ethics in scientific journals

	Topic	Authors	Journal
1.	<u>Audiovisual recording of the consenting process in clinical research: experiences from a tertiary referral centre.</u> <u>PerspectClin Res 2018; 9: 44-7</u>	Shetty PA, Maurya M, Figer BH, Thatte UM & Gogtay NJ.	
2.	An audit of minutes of Subject Expert Committee [SEC] meetings as a metric to assess the clinical research roadmap of India. Accepted for publication. Perspectives in Clinical Research.	Shetty P, Gogtay NJ, Thatte UM.	
3.	An audit of studies registered retrospectively with the clinical trials registry of India: A one year analysis. PerspectClin Res [Epub ahead of print] [cited 2018 Jul 2]. Available	Birajdar AR, Bose D, Nishandar TB, Shende AA, Thatte UM, Gogtay NJ.	from: http://www.picronline.org/preprintarticle.asp?id=235245
4.	Payment for participation in clinical research- a review of proposals submitted to the ethics committee. PerspectClin Res 2018; 9: 64-9.	Marathe PA, Tripathi RK, Shetty YC, Kuyare SS, Kamat SK, Thatte UM.	
5.	Adherence of Medical Case Reports Published In 2015 In PubMed Indexed Indian Journals to CARE 2013 Guidelines. Accepted for Publication. Indian Journal of Medical Ethics.	Ravi R, Mulkalwar A, Thatte UM & Gogtay NJ	
6.	<u>Investigator preparedness for monitoring and audits.</u> <u>PerspectClin Res 2018; 9: 95-98.</u>	Ravi R, Bose D, Gogtay NJ, Thatte UM.	
7.	An evaluation of reporting of consent declines in three high impact factor journals. Accepted for publication in "Clinical Ethics"	Figer BH, Thaker SJ, Boob M, Gogtay NJ, Thatte UM.	

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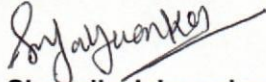
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6. Winning Prizes for papers /posters related to research ethics at conferences:

Awards won -

1. Awarded 2 nd prize in e poster to Gajbhiye SV, Surve SV, Jalgaonkar SV, Lad MS for paper titled, 'An observational study to assess completion report for compliance to research proposal to the institutional ethics committee approved protocol'; 6th National Conference of Forum for Ethics Review Committees in India FERCICON on 30th Nov - 1st Dec 2018 at Kasturba medical college, Mangalore.


Dr. Sharmila Jalgaonkar
Member Secretary
IEC-I




Dr. Snehalata Gajbhiye
Member Secretary
IEC-II