

Annual report as on 31st January 2018
INSTITUTIONAL ETHICS COMMITTEE (IEC) I & II

Established: 1987

Current SOPs Version 5, dated 26th July 2017 effective from 1st August 2017

IEC-I registered with DCGI, Re-registration No. ECR/229/Inst./MH/2013/RR-16,

IEC-II registered with DCGI, registration No ECR/417/Inst./MH/2013

Re-recognized by SIDCER-FERCAP for compliance to international standards in November 2016 for the period of four years (from 23rd Nov 2016 to 23rd Nov 2020)

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 **55 meetings (11 full board meetings and 44 SAE Subcommittee meetings)** were held in the year 2017. A total of 19 pharmaceutical sponsored projects, 1 government sponsored project, 78 other academic projects and 102 thesis / dissertations were submitted to the IEC-I for initial review during the year.

4 other academic & 2 thesis 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 2017

Year 2017	Projects reviewed	Under Process	Approved
Pharmaceutical sponsored projects	19	13	3
GOVT sponsored projects	1	1	0
Thesis	102	32	70
Other Academic	78	25	45
Total	200	71	118

In regards to sponsored studies:

Year 2017		PHARMA	GOVT
I	Total no. of projects reviewed by IEC-I	19	1
III	Type of study	Phase I	1
		Phase II	-
		Phase III	-
		Phase IV	-
		Phase II & III	-
		BABE	-
		NA	-

Serious Adverse Events:

Total 46 SAE meeting held till 31 st January 2018						
Particulars		PHARMA	GOVT	OA	THESIS	
1	Total no. of SAE at					
	Initial report	9	6	-	-	-
	Follow up report	12	5	-	-	-

	our site: causality	-	-	-	-
2	Total no. of death	1	2	-	-
3	Our site late reporting (after 24 hours)	-	-	-	-
4	Responses (query) from EC regarding our site SAEs	Query letters sent	23	-	-
		Noted letters sent	43	-	-
7	Total no. of Adverse Events (AE) reported	-	-	-	-
8	Total no. of SUSAR/CIOMS reported:	3637	-	-	41

Status of the ongoing sponsored projects of IEC-I as on 31st January 2018

Year	Pharmaceutical sponsored projects	GOVT sponsored projects	Other Academic projects	Thesis	Total
2004	0	1	0	0	1
2007	0	1	0	0	1
2010	0	1	0	0	1
2011	1	1	0	0	2
2012	3	1	0	0	4
2013	1	5	2	19	27
2014	3	4	15	32	54
2015	2	0	27	69	98
2016	9	4	44	106	163
2017	3	0	45	70	118
Total	22	18	133	296	469

Activities of the IEC-II in the year 2017

A total of 11 meetings were held in the year 2017. A total of 00 pharmaceutical sponsored projects, 4 government sponsored projects, 82 other academic projects and 106 thesis / dissertations were submitted to the IEC-II for initial review during the year.

1 thesis 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 2017

Year 2017	Total reviewed projects	Under Process	Approved
PHARMA	0	0	0
GOVT	4	1	3
Thesis	106	40	66
Other Academic	82	25	57
Total	192	66	126

Status of the ongoing academic projects as on 31st January 2018

Year	Pharmaceutical sponsored projects	GOVT sponsored projects	Other Academic projects	Thesis	Total
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2007				1	1
2009				1	1
2010			2		2
2011			1		1
2012			3		3
2013	2	1	2	54	59
2014		2	5	33	40
2015			09	59	68
2016	5	3	27	104	139
2017		3	57	66	126
Total	7	9	106	318	440

Total projects reviewed by the IEC-I & II in the year 2017

	Departments	PHARMA	GOVT	Thesis	Other Academic
1.	Anaesthesia	-	-	23	19
2.	Anatomy	-	-	-	
3.	Biochemistry	-	-	-	3
4.	Cardiology	3	-	-	-
5.	Clinical Pharmacology	1	1	-	12
6.	Chest Medicine	-	-	8	-
7.	CVTS	-	-	-	-
8.	Dermatology	1	-	5	9
9.	Dentistry	-	-	-	1
10.	Endocrinology	2	1	-	11
11.	ENT			5	-
12.	Forensic Medicine			-	-
13.	Gastroenterology	2		-	7
14.	General Surgery			10	1
15.	Hematology			-	1
16.	Medicine	1		11	7
17.	Microbiology			6	8
18.	Neurology	1		-	-
19.	Neuro surgery			-	-
20.	Neonatology			-	7
21.	Nephrology	1		-	1
22.	Nuclear medicine			-	2
23.	Obstetrics and Gynaecology	1	1	22	7
24.	Orthopaedics	1		3	2
25.	Ophthalmology	1		3	-

26.	OT			20	1
27.	Pathology			15	-
28.	Paediatrics	2		16	2
29.	Paediatrics surgery			-	-
30.	Plastic Surgery			-	2
31.	Psychiatry		1	3	9
32.	PSM		1	30	22
33.	Pharmacology & Therapeutics			2	10
34.	Physiology			4	4
35.	PT			14	2
36.	Radiology			7	1
37.	Social Service			-	-
38.	Surgical Gastroenterology			-	4
39.	Transfusion Medicine			1	3
40.	Urology	2		-	2
	TOTAL Reviewed	19	5	208	160

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 (Lay person)	Office Superintendent Indian Railway.	M.A., B.Ed.	F
9.	Dr. Santosh Kondekar	Member (External scientific expert)	Associate Professor, (Pediatrics) Topiwala National Medical College and B. Y. L. Nair Charitable Hospital, Mumbai.	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)	Assistant 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		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
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 (External Legal Expert)	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.	Mrs. Gitaali Pawaar	Member (External Lay person)	Trustee / Chairperson, Little MORE Charitable Trust, Mumbai.	B.A., D.C.A., PGDEM, M.E.M.	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.	Professor, (Obstetrics & Gynaecology) GSMC & KEMH	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 Medical College and KEM Hospital Mumbai.	MPT h	F

Alternate Members of IEC-I & IEC-II as on 31st January 2018

1.	Dr. Subodh Sirur	Member (External Legal Expert)	Consultant, Dermatology & Venerology, Mahatma Gandhi Memorial Hospital, Mumbai	MBBS, DVD, LLM	M
2.	Dr. Pradnya Talawdekar	Alternate Member (External legal Expert)	Project Manager, Ojus Medical Institute, The Tulip Star, Juhu Tara Road Juhu, Mumbai.	B.A.M.S., L.L.M.	F
3.	Mrs. Sushma Singh	Alternate Member (External legal Expert)	Advocate, High Court	B. Pharm. LL.B. LL.M Certificate in Alternative Disputes Resolution (ADR)	F
4.	Mrs. Sadhana Bhatkhande	Alternate Member (External Social)	Community Development Officer (Psychiatry) Seth GS	M.A. (in social work), Masters in counseling	F

		Scientist)	Medical College and KEM Hospital Mumbai.	and Psychotherapy, M.A. in Marathi	
5	Dr. Nivedita Chalill	Alternate Member (External Social Scientist)	Counselor and Arts Based Therapist PhD Scholar. Tata Institute Of social sciences.	M.A., Ph.D., M.Phil. in social work, B.Sc(Occupational Therapy), PG Dip in Guidance & Counseling.	F
6.	Dr. (Mrs.) Helen Joseph	Alternate Member (External Social Scientist)	-	M.S.W., M. Phil., Ph.D.	F
7.	Mrs. Manisha NaikDalal	Alternate Member (External Layperson)	-	M.Com	F
8.	Dr. Sai Kulkarni	Alternate Member (External Layperson)	-	PhD, M.A,	F

IEC-I & II Office bearers

Mrs. Janhavi Katkar, Administrative Manager, (nayanvkatkar@gmail.com)

Ms. ManaliVengurlekar, Executive Assistant, IEC-I

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

Ms. ShwetaSurve, Executive Assistant, IEC-II

Ms. Prajakta Auti, Executive Assistant, IEC-II &SAE Subcommittee

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:

- Dr. Yashashri Shetty attended the "Capacity Building Workshop on Ethics and Regulation of Clinical Trials in India" on 8th -9th Jan 2016 at Topaz Auditorium, YWCA
- Dr. Yashashri Shetty participated in ISCR- Ethics Council Monthly telecon_08-Jun-2016 -2:00 pm - 3:00 pm.
- Dr. Yashashri Shetty Faculty for "Introduction to GCP and Role of sponsor" as a part of our Good Clinical Practice workshop conducted on 8th August 2016 from 11.45 pm to 3.30 pm in the Department of Anaesthesiology library at KEMH
- Dr. Yashashri Shetty Faculty for Research methodology workshop by Dept of Dental sciences at Terna Dental College, Nerul, Navi Mumbai on "Biomedical Research: Scope and Avenues
- Dr. Yashashri Shetty Selection of Research Topic and Framing a Research Question with Group Exercises on 11th August 2016 at SEMINAR HALL, Ground floor from 08.30am -12.30 pm
- Dr. Uma Jadhav attended the "Capacity Building Workshop on Ethics and Regulation of Clinical Trials in India" on 8th -9th Jan 2016 at Topaz Auditorium, YWCA.
- Dr. Uma Jadhav participated as delegate in SIDCER Training course program to do site monitoring as a trainee surveyor at Tata Hospital Ethics Committee from 22nd August to 24th August 2016.
- Dr. Uma Jadhav faculty for Research methodology workshop by HomiBhabha Centre for Science Education, Tata Institute of Fundamental Research (TIFR) on 7th February 2016 for Post-Graduate (M.Ed) Students on "Ethics & Research".
- Sharmila Jalgaonkar, Mrs. JanhaviKatkar, PrajaktaAuti, ShwetaSurve, ManaliVengurlekar, SnehalataGajabhiye, PadmajaMarathe, ChayaVerma,

Manisha Naik Dalal Participated as delegates in a Current Regulatory Requirements for Members of Institutional Ethics Committees (An Awareness Program) on February 17-18, 2016 at Tata Memorial Hospital, Mumbai.

- Dr. Sharmila Jalgaonkar, Dr. Snehalata Gajabhiye, Dr. Yashashri Shetty, Dr. Sweta Salgaonkar and Prajakta Auti participated as delegate in alndian Society for clinical research pre-conference workshop on Causality Assessment of SAEs on 7th Jan 2016 at Trident Hotel, Mumbai.

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

- 1) Katkar Janhavi made a poster presentation about "Profile of Institutional Ethics Committee" during the 16th International Conference, "Toward Research Ethics Harmonization in Asia and the Western Pacific", organized by FERCAP on 20th to 23rd Nov 2016 at Bangkok, Thailand.

3. Publication related to research ethics in scientific journals

	Topic	Authors	Journal
1	An Audit of Protocol Deviations Submitted to an Institutional Ethics Committee of a Tertiary Care Hospital	Jalgaonkar SV, Bhide SS, Tripathi RK, Shetty YC, Marathe PA, Katkar JV, Thatte UM	PLOS ONE DOI:10.1371/journal.pone.0146334 January 6, 2016 :1-9
2	Is Coercion Involved in the Decision-Making of Medical Students Participating in Research? -A Cross-Sectional Study.	Vaidya P, Kamat S, Shetty YC, Singh KM.	Asian Bioethics Review March 2016 Volume 8, Issue 1; Pg 20-36.
3	Impact of recent regulatory notifications on the functioning of the Institutional Ethics Committee of a tertiary care teaching hospital in Mumbai	Bhide SS, Jalgaonkar SV, Katkar JV, Shetty YC, Tripathi RK, Marathe PA, Thatte UM	Indian Journal of Medical Ethics October-December 2016; Vol I, No 4 :210-14.
4	Serious Adverse Events Reports: Analysis and Outcome of Review by an Institutional Ethics Committee of a Tertiary Care Hospital in Mumbai, India.	Raakhi Tripathi, Padmaja Marathe, Sandip Kapse, Yashashri Shetty, Sandhya Kamat, Urmila Thatte	Journal of Empirical Research on Human Research Ethics 1556264616654809, first published on July 2016 11: 267-273 doi:10.1177/1556264616654809.
5	Abortion Rights: At Last, A Judgment of Shining Hope!	Johari V, Jadhav U.	Indian Journal of Medical Ethics. (Accepted for Publication)
6	An audit of the approval letters issued by Drugs Controller General of India to Ethics Committees in India	Bhide SS, Katkar JV, Mourya M, Gogtay NJ, Thatte UM.	Published in PICR Vol 7 /Issue 4/ Oct-Dec 2016 www.picronline.org

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

- a) Mrs. Janhavi Katkar secured first place for poster presentation about "Profile of Institutional Ethics Committee" during the 16th Annual International Conference of the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP) on 20th to 23rd Nov 2016 at Bangkok, Thailand.

- b) Vaidya PH, Kamat SK, **Shetty YC**, Singh KNM. Is coercion involved in medical student's Participation in research studies? **Kritarth** presented the paper at 195th Staff society e-poster presentation on 24th Feb 2016 at Seth GSMC & KEM H and secured **first place** .
- c) Study on "An Audit Of Approval Letters Issued By The Drugs Controller General Of India (DCGI) To Ethics Committees" by Bhide SS, **Katkar JV**, Maurya MR, Gogtay NJ, **Thatte UM** won **first prize** in poster session at ISCR Conference- 2016. Presented by Dr. SS Bhide, Assoc. Prof., Dept. of Pharmacology & Therapeutics.

Dr. Sharmila Jalgaonkar
Dr. Sharmila Jalgaonkar
Member Secretary
IEC-I

Dr. Snehalata Gajbhiye
Dr. Snehalata Gajbhiye
Member Secretary
IEC-II

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