

INSTITUTIONAL ETHICS COMMITTEE (IEC)I& II

Established: 1987

Current SOPs Version 4, 1st September 2013

Received the SIDCER re-recognition award for compliance to international standards in November 2012

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 in the year 2015

A total of **47 meetings (10 full board meetings, 1 SOP training meeting, and 36 SAE Subcommittee meetings)** were held in the year 2015. A total of 10 pharmaceutical sponsored projects, 4 government sponsored projects, 58 other academic projects and 101 thesis / dissertations were submitted to the IEC-I for initial review during the year.

None of the Pharmaceutical 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 2015

Year 2015	Projects reviewed	Under Process	Approved
Pharmaceutical sponsored projects	10	9	1
GOVT sponsored projects	4	2	2
Thesis	101	19	82
Other Academic	58	29	29
Total Reviewed Projects	173	59	114

In regards to sponsored studies:

		Year 2014	PHARMA	GOVT
I	Total no. of projects reviewed by IEC-I		10	4
II	Total ongoing projects		1	2
III	Type of study	Phase III	7	-
		Phase III B	1	-
		Phase IV	1	-
		Bioequilance	1	-
		NA	-	4

	Departments	PHARMA	GOVT	Thesis	Other Academic
1.	Anaesthesia	1	-	13	6
2.	Anatomy	-	-	-	1
3.	Biochemistry	1	-	1	-
4.	Cardiology	1	-	-	3
5.	Clinical Pharmacology	2	1	-	4

6.	Chest Medicine	-	1	-	1
7.	Dermatology	-	-	1	-
8.	Endocrinology	-	-	-	1
9.	ENT	-	-	3	-
10.	Forensic Medicine	-	-	-	1
11.	Gastroenterology	-	-	-	5
12.	General Surgery	-	-	5	1
13.	Hematology	-	-	-	1
14.	Medicine	1	-	10	7
15.	Microbiology	-	-	1	2
16.	Neurology	-	-	-	1
17.	Neuro surgery	-	-	-	-
18.	Neonatology	-	-	-	-
19.	Nephrology	-	-	-	2
20.	Nuclear medicine	-	-	-	-
21.	Obstetrics and Gynaecology	-	1	17	-
22.	Orthopaedics	-	-	4	1
23.	Ophthalmology	3	-	-	1
24.	OT	-	-	3	-
25.	Pathology	-	-	2	1
26.	Paediatrics	1	-	7	1
27.	Paediatrics surgery	-	-	-	1
28.	Plastic Surgery	-	-	-	1
29.	Psychiatry	-	-	5	3
30.	PSM	-	-	12	7
31.	Pharmacology & Therapeutics	-	1	1	3
32.	Physiology	-	-	2	-
33.	PT	-	-	7	-
34.	Radiology	-	-	4	-
35.	Surgical Gastroenterology	-	-	-	1
36.	Transfusion Medicine	-	-	-	-
37.	Urology	-	-	-	2
	TOTAL Reviewed	10	4	98	58

Serious Adverse Events:

Total 36 SAE meeting held in year 2015						
	Particulars		PHARMA	GOVT	OA	Thesis
1	Total no. of SAE at our site:	Initial report	13	-	-	-
		Follow up report	30	-	-	-
		causality	2	-	-	-
2	Total no. of death		1	-	-	-
3	Our site late reporting (after 24 hours)		1	-	-	-
4	Responses (query) from EC regarding our site SAEs	Query letters sent	38	-	-	-
		Noted letters sent	50	-	-	-
7	Total no. of Adverse Events (AE) reported		-	-	-	-
8	Total no. of SUSAR/CIOMS reported:		2870	-	-	-

Status of the ongoing sponsored projects of IEC-I as on 30th Nov 2015

1 pharmaceutical sponsored project submitted in the Year 2001 is ongoing.
 1 government sponsored project submitted in the Year 2004 is ongoing
 1 pharmaceutical sponsored project submitted in the Year 2005 is ongoing
 2 government sponsored projects submitted in the Year 2007 are ongoing
 4 government sponsored projects submitted in the Year 2009 are ongoing
 2 pharmaceutical and 1 government sponsored projects submitted in the Year 2010 are ongoing
 1 pharmaceutical and 5 government sponsored projects submitted in the Year 2011 are ongoing
 5 pharmaceutical and 3 government sponsored projects submitted in the Year 2012 are ongoing
 8 pharmaceutical and 6 government sponsored projects submitted in the Year 2013 are ongoing
 6 pharmaceutical and 5 government sponsored projects submitted in the Year 2015 are ongoing

Status of the ongoing academic projects of IEC-I as on 30th Nov 2015

8 thesis and 2 other academic project submitted in the year 2012 are ongoing.
 58 thesis and 25 other academic projects submitted in the year 2013 are ongoing.
 87 thesis and 41 other academic projects submitted in the year 2014 are ongoing.

Constitution of the IEC-I as on 30th Nov 2015**Member list of Institutional Ethics Committee – I (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	Assistant Professor (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F
3.	Dr. Smrati Bajpai	Member	Assistant Professor (Medicine) Seth GS Medical College and KEM Hospital Mumbai.	M.D., DNB.	F

4.	Dr. Yashashri Shetty	Member	Associate Professor (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai.	M.D., DBM.	F
5.	Dr. (Mrs.) Uma Jadhav	Member (Social scientist)	Community Development Officer (Obstetrics and Gynaecology) Seth GS Medical College and KEM Hospital Mumbai.	M.S.W., L.L.B, Ph.D Scholar (Health Systems Studies)	F
6.	Ms. Veena Johari	Member (External Legal Expert)	Independent Lawyer	L.L.B.	F
7.	Ms. Gitaali Pawaar	Member (External Lay person)	Trustee / Chairperson, Little MORE Charitable Trust, Mumbai.	B.A., D.C.A., PGDEM, M.E.M.	F
8.	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
9.	Dr. Rujuta Mehta	Member (External Scientific Expert)	HOD PaediatricOrthopaedic, Bai JerbaiWadiaa Hospital for children, Mumbai.	M.S., DNB.	F
10.	Dr. Mohan Desai	Member	Professor(Orthopedics) Seth GS Medical College and KEM Hospital Mumbai.	M.S, MCPS	M
11.	Dr. Sona Dave	Member (External Scientific Expert)	Professor, (Anaesthesiology) TNMC & BYL Nair Charitable Hospital, Mumbai.	M.D., DA., DNB	F
12.	Dr. Sharad Patel	Member	Associate Professor (Adhoc) (Physiology) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	M
13.	Ms. Jaimala Shetye	Member	Associate Professor (Physiotherapy) Seth GS Medical College and KEM Hospital Mumbai.	MPTH	F
14.	Dr. Alka A. Subramanyam	Member (External Scientific Expert)	Assistant Professor (Psychiatry) TNMC & BYL Nair Charitable Hospital, Mumbai.	M.D., D.N.B., DHA.	F
15.	Dr. Urmila Thatte	Member	Professor & Head (Clinical Pharmacology) Seth GS Medical College and KEM Hospital Mumbai.	M.D., DNB., Ph.D.	F

Activities of the **IEC-II** in the year 2015

A total of **11** meetings (**10 full board meetings, 1 SOP training meeting**) were held in the year 2015. A total of 8 pharmaceutical sponsored projects, 4 government sponsored projects, 61 other academic projects and 98 thesis / dissertations were submitted to the IEC-II for initial review during the year.

None of the Pharmaceutical projects were 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 2015

Activities of the IEC-II in the year 2015

Year 2011	Total reviewed projects	Under Process	Approved
PHARMA	8	4	4
GOVT	1	1	-
Thesis	98	20	78
Other Academic	61	27	34
Total	168	52	116

Status of the ongoing sponsored projects of IEC-II as on 30th Nov 2015

1 GOVT sponsored project submitted in the Year 2012 is ongoing
 2Pharma sponsored and 4 government sponsored projects submitted in the Year 2013 are ongoing
 8 Pharma sponsored and 3 government sponsored projects submitted in the Year 2014 are ongoing

Status of the ongoing academic projects as on 30th Nov 2015

2 Thesis projects submitted in the Year 2007 are ongoing.
 1 Thesis and 2 other academic project submitted in the Year 2008 are ongoing.
 2 Thesis submitted in the Year 2009 are ongoing.
 13 thesis and 11 other academic projects submitted in the year 2010 are ongoing.
 3 thesis and 14 other academic projects submitted in the year 2011 are ongoing.
 89thesis and 12 other academic projects submitted in the year 2012 are ongoing.
 63thesis and 32 other academic projects submitted in the year 2013 are ongoing.
 107 thesis and 47 other academic projects submitted in the year 2014 are ongoing.

Year 2015		PHARMA	GOVT
I	Total no. of projects reviewed	8	1
II	Total ongoing projects	4	1
III	Type of study		
	Phase I	1	-
	Phase III	5	-
	Phase IV	2	-
	NA	-	1

	Departments	PHARMA	GOVT	Thesis	Other Academic
1	Anaesthesia	-	-	14	6
2	Anatomy	-	-	-	2
3	Biochemistry	-	-	-	-
4	Cardiology	-	-	-	3
5	Clinical Pharmacology	-	-	-	8
6	Chest Medicine	-	-	2	-
7	Dermatology	-	-	2	2
8	Endocrinology	-	-	-	1
9	ENT	-	-	2	-
10	Forensic Medicine	-	-	2	-
11	Gastroenterology	-	-	-	3
12	General Surgery	-	-	7	-
13	Hematology	-	-	-	-
14	Medicine	1	-	11	2
15	Microbiology	-	-	2	2
16	Neurology	-	-	-	3
17	Neuro surgery	-	-	-	-
18	Neonatology	-	-	-	-
19	Nephrology	-	-	-	7
20	Nuclear medicine	-	-	1	-
21	Obstetrics and Gynaecology	-	-	22	1
22	Orthopaedics	1	-	4	1
23	Ophthalmology	5	-	3	-
24	OT	-	-	1	-
25	Pathology	-	-	3	1
26	Paediatrics	1	-	3	1
27	Paediatrics surgery	-	-	-	1
28	Plastic Surgery	-	-	-	-
29	Psychiatry	-	1	3	3
30	PSM	-	-	5	10
31	Pharmacology & Therapeutics	-	-	1	1
32	Physiology	-	-	2	-
33	PT	-	-	4	1
34	Radiology	-	-	3	-
35	Surgical Gastroenterology	-	-	-	1
36	Transfusion Medicine	-	-	1	-
37	Urology	-	-	-	1
	TOTAL Reviewed	8	1	98	61

Constitution of IEC-II

	Name	Position on IEC II	Designation & Affiliation	Qualification	Gender
1.	Dr. Sangeeta Desai	Chairperson (External)	Professor and Office in Charge, Molecular Pathology, Tata Memorial Centre, Mumbai.	M.D., DTM.	F
2.	Dr. Snehalata Gajbhiye	Member Secretary	Assistant Professor (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai.	M.D., FICS.	F
3.	Dr. Yuvaraj B. Chavan	Member	Professor (Additional) (PSM) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	M
4.	Dr. Shobha Itollikar	Member (External)	-	M.D., D.N.B.	F
5.	Dr. Padmaja Marathe	Member	Professor (Additional) (Pharmacology & Therapeutics) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F
6.	Dr. Nilesh Thakre	Member (External Social Scientist)	Assistant 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
7.	Dr. Subodh Sirur	Member (External Legal Expert)	Consultant, Dermatology & Venerology, Mahatma Gandhi Memorial Hospital, Mumbai	MBBS, DVD, LLM	M
8.	Ms. Leena Pednekar	Member (External Lay person)	Chief Dietician, Mahatma Gandhi Memorial Hospital, Mumbai.	P.G. in the area of Dietetics and Applied Nutrition.	F
9.	Dr. Padmaja Samant	Member	Professor, (Obstetrics & Gynaecology) Seth GS Medical College and KEM Hospital Mumbai.	Professor, (Obstetrics & Gynaecology) GSMC & KEMH	F
10.	Dr. Santosh Kondekar	Member (External)	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
11.	Dr. Sujata Aiyer	Member	Associate Professor, (Orthopaedics) Seth GS Medical College and KEM Hospital Mumbai.	M.S., F.R.C.S.(UK), General Medical Council (UK), ECFMG.	F

12.	Dr. Sweta Salgaonkar	Member	Professor (Anesthesiology) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F
13.	Dr. Sunil Kuyare	Member (External)	Assistant Professor, (Microbiology) Dr.R.N.Cooper Municipal General Hospital Bhaktivedanta Swami Marg,JVPD,Juhu,Mumbai.	M.D., PGDHA,FME.	M
14.	Dr. Shilpa Adarkar	Member	Assistant Professor,(Psychiatry) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F
15.	Mrs. Chhaya Verma	Member	Professor (Physiotherapy) Seth GS Medical College and KEM Hospital Mumbai.	M.PTh.	F
Alternate Members of IEC-I & IEC-II effective as on 30th Nov 2015					
1.	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
2.	Mrs. Sushma Singh	Alternate Member (External legal Expert)	-	B. Pharm. LL.B. LL.M Certificate in Alternative Disputes Resolution (ADR)	F
3.	Ms. Nivedita Chalill	Alternate Member (External Social Scientist)	-	M.A., Ph.D., M.Phil in social work, B.Sc(Occupational Therapy), PG Dip in Guidance & Counseling.	F
4.	Dr. (Mrs.) Helen Joseph	Alternate Member (External Social Scientist)	-	M.S.W., M. Phil., Ph.D.	F
5	Mrs. Sharmila Kher	Alternate Member (External Layperson)	-	M. SC. Part 1 (Biotechnical science), Dip. In Journalism, PGDHA	F
6.	Mrs. Manisha Naik Dalal	Alternate Member (External Layperson)	-	M.Com	F
7.	Mrs. Manju Manda	Alternate Member (External Layperson)	Section officer Railways	B.Sc. Pharmacy	F

IEC-I & II Office bearers

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

Ms. Manali Vengurlekar, Executive Assistant

Ms. Shweta Surve, Executive Assistant

Ms. Prajakta Auti, Executive Assistant, SAE Subcommittee

Mr. Mangesh Khochade, Office Attendant

Mr. Vijay Chavan, Office Attendant

Contact details: Email: iec-1@kem.edu, iec-2@kem.edu,

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Activities

- Training given by IEC member Dr. Padmaja Samant:
 1. Faculty for NIRRH GCP Training Program for the Project entitled :“Premature Menopause in North East: A risk Factors study ”lecture on ‘Informed Consent’- 19th September 2014
 2. Coordinated and facilitated GCP workshop for RMOs 24th September 2014
 3. Coordinated and conducted 3 Basic workshops in Research Methodology for Residents and faculty in Feb, March 2015 and November 2015
- Training given by IEC member Dr. Snehalata Gajbhiye:
 1. Delivered lectures on “Ethics in Clinical Research” in Research Methodology and Biostatistics Workshop, for P.D. Hinduja College of Nursing held on 2nd Dec 2015.
 2. Delivered lectures on “Sampling methods and sample size calculation” in Research Methodology and Biostatistics Workshop, for Obstetric & Gynecology department of Seth GS Medical College and KEM Hospital held on 18th November 2015.
 3. Faculty for GCP Training Program for the session on “Roles and responsibilities of IEC’ organized by Department of Pharmacology and Therapeutics on 28th October 2015
 4. Delivered lecture on “Qualitative research” and ‘Survey as research tools’ in YMT Dental College and Hospital held on 30th September 2015
 5. Delivered lecture on “Qualitative research” and ‘Clinical study designs’ for the in MGM Dental College and Hospital held on 10th August 2015
 6. Delivered lecture on “Ethics in clinical research” and ‘Survey as research tools’ for the Pediatric department in Seth GS Medical College and KEM Hospital held on 6th August 2015.
 7. Delivered lecture on “Ethics in clinical research” for Pediatric department in Seth GS Medical College and KEM Hospital held on 6th August 2015.
 8. Delivered lecture on “Ethics in clinical research” for Pediatric department in Seth GS Medical College and KEM Hospital held on 24th June 2015.
 9. Delivered lecture on “Ethics in clinical research” and ‘Safety review and reporting’ in Sommaiya Medical College and Hospital held on 31st July 2015
 10. Delivered lecture on “Survey as research tool” and ‘Safety review and reporting and ‘Inclusion and exclusion criteria’ in Terna Dental College and Hospital held on 16th June 2015
 11. Delivered lecture on “Ethics in clinical research” in Ayurveda College and Hospital Sion held on 4th Feb 2015.
 12. Delivered lecture on “Guidelines on clinical research” for the course Postgraduate Diploma in Clinical Research in DY Patil Medical College and Hospital held on 6th September 2014

Dr. Sharmila Jalgaonkar
Member Secretary
IEC-I

Dr. Snehalata Gajbhiye
Member Secretary
IEC-II