

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 2014

A total of **thirty nine meetings (12 full board meetings, 1 SOP training meeting, 2 emergency meetings and 24 SAE Subcommittee meetings)** were held in the year 2014. A total of 9 pharmaceutical sponsored projects, 5 government sponsored projects, 63 other academic projects and 106 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 2014

Year 2014	Projects reviewed	Under Process	Approved	Rejected	Disposed
Pharmaceutical sponsored projects	9	6	3	-	
GOVT sponsored projects	5	4	1	-	
Thesis	106	20	83	1	2
Other Academic	63	31	29		3
Total Reviewed Projects	183	61	116	1	5

In regards to sponsored studies:

		Year 2014	PHARMA	GOVT
I	Total no. of projects reviewed by IEC-I		9	5
II	Total ongoing projects		3	1
III	Type of study			
	Phase III		8	-
	Phase III B		1	-
	NA		-	5

	Departments	PHARMA	GOVT	Thesis	Other Academic
1.	Anaesthesia	-	-	8	5
2.	Cardiology	1	-	-	2
3.	Clinical Pharmacology	2	-	-	4
4.	Chest Medicine	-	-	1	-
5.	Dermatology	-	-	1	1
6.	Endocrinology	-	-	-	3
7.	ENT	-	-	1	-
8.	Forensic Medicine	-	-	1	-
9.	Gastroenterology	-	1	-	3
10.	General Surgery	1	1	3	2
11.	Hematology	1	-	-	-
12.	Medicine	-	1	10	-
13.	Microbiology	-	-	2	3
14.	Neuro surgery	-	-	-	1
15.	Neonatology	-	-	-	2
16.	Nephrology	-	-	-	4
17.	Nuclear medicine	-	-	1	1
18.	Obstetrics and Gynaecology	1	2	8	2
19.	Orthopaedics	-	-	5	-
20.	Ophthalmology	3	-	1	-
21.	OT	-	-	4	-
22.	Pathology	-	-	11	3
23.	Paediatrics	-	-	13	1
24.	Plastic Surgery	-	-	-	5
25.	Psychiatry	-	-	3	4
26.	PSM	-	-	8	8
27.	Pharmacology & Therapeutics	-	-	2	5
28.	Physiology	-	-	3	4
29.	PT	-	-	13	-
30.	Radiology	-	-	4	-
31.	Surgical Gastroenterology	-	-	1	-
32.	Transfusion Medicine	-	-	1	-
33.	Urology	-	-	1	-
	TOTAL Reviewed	9	5	106	63

Serious Adverse Events:

	Particulars	PHARMA	GOVT	OA	Thesis	
1	Total no. of SAE at our site:	Initial report	3	-	-	-
		Follow up report	5	-	-	-
		causality	-	-	-	-
2	Total no. of death	-	-	-	-	
3	Our site late reporting (after 24 hours)	-	-	-	-	
4	Responses (query) from EC regarding our site SAEs	Query letters sent	8	-	-	-
		Noted letters sent	17	-	-	-
7	Total no. of Adverse Events (AE) reported	-	-	-	-	
8	Total no. of SUSAR/CIOMS reported:	1877	-	-	-	

Status of the ongoing sponsored projects of IEC-I as on 19th December 2014

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
 1 pharmaceutical sponsored project submitted in the Year 2008 is ongoing
 4 government sponsored projects submitted in the Year 2009 are ongoing
 3 pharmaceutical and 2 government sponsored projects submitted in the Year 2010 are ongoing
 9 pharmaceutical and 7 government sponsored projects submitted in the Year 2011 are ongoing
 5 pharmaceutical and 4 government sponsored projects submitted in the Year 2012 are ongoing
 8 pharmaceutical and 8 government sponsored projects submitted in the Year 2013 are ongoing

Status of the ongoing academic projects of IEC-I as on 19th December 2013

8 thesis and 1 other academic project submitted in the year 2012 are ongoing.
 58 thesis and 34 other academic projects submitted in the year 2013 are ongoing.

Constitution of the IEC-I as on 19th December 2014

Member list of Institutional Ethics Committee – I (IEC-I)

	Name	Position on IEC I	Designation & Affiliation	Qualification	Gender
1.	Dr. Jigeeshu V. Divatia	Chairperson (External)	Professor and Head, Anesthesiology, Tata Memorial Hospital, Mumbai.	M.D.	M
2.	Dr. Vikram Londhey	Co-Chairperson (External)	Associate Professor (Medicine & Rheumatology Clinic) TNMC & BYL Nair Charitable Hospital, Mumbai.	M.D.	M

3.	Dr. Shruti Bhide	Member Secretary	Associate Professor (Pharmacology & Therapeutics) GSMC & KEMH	M.D.	F
4	Mrs. Sadhana Bhatkhande	Alternate Member (Social Scientist)	Medical Social Worker (Psychiatry) GSMC & KEMH	M.A. (in social work), Masters in counseling and Psychotherapy.	F
5	Dr. Smrati Bajpai	Member	Assistant Professor (Medicine) GSMC & KEMH	M.D., DNB.	F
6	Dr. Anahita Chauhan	Member	Professor (Additional) (Obstetrics & Gynecology) GSMC & KEMH	M.D.	F
7	Mrs. Manisha NaikDalal	External Layperson	-	M.Com	F
8	Dr. BibhasDasGupta	Member	Professor (Orthopedics)GSMC & KEMH	M.S.	M
9	Dr. AparnaDeshpande	Member	Professor, (Surgery) GSMC & KEMH	M.S, D.N.B.E F.I.A.G.E.S	F
10	Dr. Yuvaraj B. Chavan	Member	Professor (Additional) (Preventive and Social Medicine) GSMC & KEMH	M.D.	M
11	Dr. Arpit Sharma	Member	Assistant Professor (ENT) GSMC & KEMH	M.S., DORL, D.N.B	M
12	Dr. Subodh Sirur	(External Legal Expert)	Consultant, Dermatology & Venerology, Mahatma Gandhi Memorial Hospital, Mumbai	MBBS, DVD, LLM	M
13	Dr. Urmila Thatte	Member	Professor & Head (Clinical Pharmacology) GSMC & KEMH	M.D., DNB., Ph.D.	F
14	Dr. Raakhi Tripathi	Member	Associate Professor (Pharmacology & Therapeutics) GSMC & KEMH	M.D.	F
15	Mrs. Chhaya Verma	Member	Professor (physiotherapy) GSMC & KEMH	MPTth	F

Activities of the IEC-II in the year 2014

A total of **thirteen meetings (12 full board meetings, 1 SOP training meeting)** were held in the year 2014. A total of 9 pharmaceutical sponsored projects, 5 government sponsored projects, 64 other academic projects and 105 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 2014

Activities of the IEC-II in the year 2014

Year 2011	Total reviewed projects	Under Process	Approved	Rejected	Terminated	Disposed
PHARMA	9	7	1	-	-	1
GOVT	5	4	1	-	-	-
Thesis	105	17	88			
Other Academic	64	31	28			5
Total	183	59	118			6

Status of the ongoing sponsored projects of IEC-II as on 19th December 2014

2 out of 8 pharmaceutical sponsored projects submitted in the Year 2013 are ongoing
 2 out of 5 government sponsored projects submitted in the Year 2013 are ongoing

Status of the ongoing academic projects as on 31st December 2012

2 Thesis projects submitted in the Year 2007 are ongoing.
 1 Thesis and 1 other academic project submitted in the Year 2008 are ongoing.
 13 thesis and 62 other academic projects submitted in the year 2010 are ongoing.
 3 thesis and 56 other academic projects submitted in the year 2011 are ongoing.
 160 thesis and 57 other academic projects submitted in the year 2012 are ongoing.
 114 thesis and 63 other academic projects submitted in the year 2013 are ongoing.

Year 2014		PHARMA	GOVT
I	Total no. of projects reviewed	9	5
II	Total ongoing projects	1	1
III	Type of study	Phase I	-
		Phase II	1
		Phase II / III	1
		Phase III	3
		Phase IV	2
		Bioequivalence	1
		NA	1

	Departments	PHARMA	GOVT	Thesis	Other Academic
1.	Anatomy	-	-	1	1
2.	Anaesthesia	-	-	16	3
3.	Biochemistry	-	-	-	1
4.	Cardiology	-	-	-	2
5.	Clinical Pharmacology	1	1	-	1
6.	Chest Medicine	-	-	3	1
7.	Dermatology	1	-	2	4
8.	Endocrinology	1	-		2
9.	ENT	-	-	3	-
10.	Forensic Medicine	-	-	1	-
11.	Gastroenterology	1	-	-	4
12.	General Surgery	-	-	5	2
13.	Infection diseases	-	-	-	1
14.	Medicine	1	3	8	1
15.	Microbiology	-	1	4	3
16.	Neurology	1	-	-	-
17.	Nephrology	-	-	-	5
18.	Neonatology	-	-	-	5
19.	Obstetrics and Gynaecology	1	-	3	1
20.	Orthopaedics	-	-	6	1
21.	Ophthalmology	1	-	2	-
22.	OT	-	-	5	3
23.	Pathology	-	-	6	1
24.	Paediatrics	-	-	8	-
25.	Plastic Surgery	-	-	-	2
26.	Psychiatry	-	-	2	7
27.	PSM	-	-	10	6
28.	Pharmacology & Therapeutics	1	-	1	4
29.	Physiology	-	-	2	1
30.	Physiotherapy	-	-	10	1
31.	Radiology	-	-	6	-
32.	Surgical Gastroenterology	-	-	-	1
33.	Transfusion Medicine	-	-	1	-
	Total Reviewed	9	5	105	64

Constitution of IEC-II

	Name	Position on IEC II	Designation & Affiliation	Qualification	Gender
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1.	Dr. Kamal Hazari.	Chairperson External	(Former Sr. Deputy Director - NIRRH – ICMR (Mumbai)	M.D,D.G.O, DFP	F
2.	Dr. Kaizad Damania.	Co -Chairperson (External Scientific Expert)	Professor (Obstetrics & Gynaecology) N. Wadia Maternity Hospital	M.D.,DNB., F.C.P.S.,D.G.O., D.F.P.	M
3.	Dr. Sharmila Jalgaonkar	Member Secretary	Assistant Professor (Pharmacology &Therapeutics) GSMC & KEMH	M.D.	F
4	Mr. Hemant Nandgaonkar	Joint Member Secretary	Assistant Professor (Occupational Therapy) GSMC & KEMH	M.Sc.	M
5	Dr. ShilpaAdarkar	Member	Assistant Professor,(Psychiatry) GSMC & KEMH	M.D.	F
6	Dr. Mohan Desai	Member	Professor(Orthopedics) GSMC & KEMH	M.S, MCPS	M
7	Mrs. ManjuManda	Member(External Layperson)	Section officer Railways	B.Sc. Pharmacy	F
8	Dr. Milind Nadkar	Member	Professor, (Medicine) GSMC & KEMH	M.D., FICP	M
9	Dr. SwetaSalgaonkar	Member	Professor (Anesthesiology) GSMC & KEMH	M.D.	F
10	Dr. PadmajaSamant	Member	Professor, (Obstetrics & Gynaecology) GSMC & KEMH	Professor, (Obstetrics & Gynaecology) GSMC & KEMH	F
11	Dr. Yashashri Shetty	Member	Associate Professor (Pharmacology & Therapeutics) GSMC & KEMH	M.D., DBM.	F
12	Dr. DN Shenvi	Member	Professor(Physiology) GSMC & KEMH	M.D.	F
13	Mrs. Sushma Singh.	Member (External legal Expert)	-	B. Pharm. LL.B. LL.M Certificate in Alternative Disputes Resolution (ADR)	F
14	Dr. Pradeep Vaideeswar	Member	Associate Professor Pathology	M.D.	M
15	Dr. NileshThakre.	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, PGDICP., Dip TD.	M
Alternate Members of IEC-I & II					

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	Dr. Sadhana Mahashabde.	Alternate Member (External legal Expert)	Advocate High Court	B.Sc., LLB, LLM, PhD.	F
3	Mr. Yatin Khochare	Alternate Member (External legal Expert)	Advocate, Bar Council of Maharashtra & Goa. (Practice areas: Drugs & Cosmetics, healthcare, food laws & others)	B.Sc., L.L.B., Dip in Medical Jurisprudence and forensic science.	M
4	Mrs. Sharmila Kher	Alternate Member (External Layperson)	-	M. SC. Part 1 (Biotechnical science), Dip. In Journalism, PGDHA	F
5	Mrs. Sameena Maldar.	Alternate Member (External Layperson)	-	S.Y.B.A.	F
6	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
7.	Dr. Helen Joseph	Alternate Member (External Social Scientist)	-	M.S.W., M. Phil., Ph.D.	F

IEC-I & II Office bearers

IEC-I	IEC-II
Mrs. Janhavi Katkar, Administrative Manager (nayanvkatkar@gmail.com)	
Direct no.: 24122188	
Mr. Shyam Tawde, Deputy Manager	Ms. Deepika Paradkar, Deputy Manager
Ms. Manali Vengurlekar, Senior Executive Assistant	Ms. Shweta Surve, Senior Executive Assistant
Ms. Prajakta Auti, Executive Assistant, SAE Subcommittee	
Mr. Mangesh Khochade, Office Attendant	Mr. Naresh Bhawale, Office Assistant
Contact details: Email: iec-1@kem.edu , iec-2@kem.edu , Direct no.: 24122188	

Significant achievements and activities of the IEC-I & II in the year 2014

1. A] Training programs organized by IECs:

- a) Organized half day Workshop for investigators on “Good Clinical Practice” for investigators on 13th May 2014 at Seminar Hall of Dept. of Clinical Pharmacology of Seth G. S. Medical College and K. E. M. Hospital, Mumbai, Maharashtra.
- b) Organized half day Workshop for investigators on “Good Clinical Practice” for investigators on 25th June 2014 at MET cell college building of Seth G. S. Medical College and K. E. M. Hospital, Mumbai, Maharashtra.
- c) Organized half day Workshop for investigators on “Good Clinical Practice” for investigators on 22nd July 2014 at MET cell college building of Seth G. S. Medical College and K. E. M. Hospital, Mumbai, Maharashtra.

B] Training programs attended by IEC member / staff:

- 1) Dr. S.S. Bhide and Mrs. Janhavi Katkar participated as ‘Trainee Surveyor’ in International Course on Surveying and Evaluating Ethical Review Practices, National Institute for Research in Reproductive Health (NIRRH), Mumbai, India held from 11th to 14th August 2014.

2. a) Presented papers related to research ethics at conferences:

1. Assessment of protocol deviations submitted to Institutional Ethics Committee (IEC) of tertiary care hospital **Dr SV Jalgaonkar***, Dr SS Bhide*, Dr RK Tripathi*, Dr YC Shetty*, Dr PA Marathe*, Mrs. Janhavi Katkar, Dr. UM Thatte Presented at FERCAP -2014 held from 23rd Nov. to 26th Nov. 2014 at Tagaytay City, in Philippines.
2. Impact of recent regulatory guidelines on the functioning of Institutional Ethics Committee at a Tertiary care Hospital In Mumbai, India.” Presented by **Dr. Shruti Bhide** Dr SV Jalgaonkar, Dr RK Tripathi, Dr YC Shetty, Dr PA Marathe, Mrs. Janhavi Katkar, Dr. UM Thatte at FERCAP - 2014 held from 23rd Nov. to 26th Nov. 2014 at Tagaytay City in Philippines

b) Presented posters related to research ethics at conferences:

1. **Profile of Institutional Ethics Committee- poster presented at** FERCAP -2014 held from 23rd Nov. to 26th Nov. 2014 at Tagaytay City in Philippines.

3. Publication related to research ethics in scientific journals

1. SS Kuyare¹, PA Marathe², YC Shetty², SK Kamat², JV Katkar³, UM Thatte⁴ “A retrospective analysis of the queries raised by the institutional ethics committees of a teaching hospital”. J Postgrad Med [serial online] 2014[cited 2014 Nov 10];60:46-50. Available from: <http://www.jpgmonline.com/text.asp?2014/60/1/46/128808>
2. Shetty YC, Jadhav KS, Saiyed AA, Desai AU. Are institutional review board ready for active continuing review?. Perspect Clin Res 2014;5:11-5.
3. Shetty YC, SaiyedAA . Analysis of warning letters issued by the United States Food and Drug Administration to Clinical Investigators, Institutional Review Boards and Sponsors: A retrospective study”. J Med Ethics 2014;0:1–6. doi:10.1136/medethics-2013-101829
4. Patwardhan S, Gogtay NJ, Thatte U, Pramesh CS. Quality and completeness of data documentation in an investigator-initiated trial versus an industry-sponsored trial. Indian J Med Ethics. 2014 Jan-Mar;11(1):19-24.

5. Kuyare MS1, Taur SR2, Thatte UM Establishing Institutional Research Ethics Committees: Challenges and Solutions - A Review of Literature. Indian Journal of Medical Ethics, 2014

National Surveyor

Dr. Y.C. Shetty participated as '**National Surveyor**' in **International Course** on Surveying and Evaluating Ethical Review Practices, National Institute for Research in Reproductive Health (NIRRH), Mumbai, India along with the lead surveyor Dr Paul kumaran and Dr.Sangeeta Desai with Christina Torres (FERCAP coordinator) and DrVasanthaMuthuswamy (FERCI coordinator) held from 11th to 14th August 2014

Dr. Shruti Bhide
Member Secretary
IEC-I

Dr. Sharmila Jalgaonkar
Member Secretary
IEC-II