

## INSTITUTIONAL ETHICS COMMITTEE (IEC) I & II

Established: 1987

Current SOPs Version 4, 1<sup>st</sup> 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 2013

A total of **fifty meetings (12 full board meetings, 1 SOP training meeting and 37 SAE Subcommittee meetings)** were held in the year 2013. A total of 35 pharmaceutical sponsored projects, 10 government sponsored projects, 49 other academic projects and 52 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 2013

Year 2013	Projects reviewed	Under Process	Approved	Rejected	Terminated
Pharmaceutical sponsored projects	35	20	2	-	13
GOVT sponsored projects	10	2	6	1	-
Thesis	52	8	42	1	1
Other Academic	49	30	16	3	-
<b>Total Reviewed Projects</b>	<b>146</b>	<b>60</b>	<b>66</b>	<b>5</b>	<b>14</b>

In regards to sponsored studies:

		Year 2013	PHARMA	GOVT
<b>I</b>	<b>Total no. of projects reviewed by IEC-I</b>		<b>35</b>	<b>10</b>
<b>II</b>	<b>Total ongoing projects</b>		<b>3</b>	<b>6</b>
<b>III</b>	<b>Type of study</b>	Phase I	2	-
		Phase II	4	-
		Phase III	20	1
		Phase III B	1	-
		Phase IV	4	-
		NA	1	9
		Pilot	1	-
		Device	1	-
		Device Phase II	1	-

	Departments	PHARMA	GOVT	Thesis	Other Academic
1.	Anatomy	-	-	-	1
2.	Anaesthesia	-	-	4	4
3.	Biochemistry	-	-	1	-
4.	Cardiology	3	-	-	-
5.	Clinical Pharmacology	3	1	-	1
6.	Chest Medicine	-	-	1	-
7.	Endocrinology	15	-	-	-
8.	ENT	-	-	-	-
9.	Gastroenterology	1	2	1	3
10.	General Surgery	2	-	4	1
11.	Infection diseases	-	-	-	1
12.	Hematology	1	-	-	1
13.	Medicine	3	2	4	1
14.	Neurology	-	-	-	2
15.	Neonatology	-	1	-	3
16.	Nephrology	1	-	1	2
17.	Obstetrics and Gynaecology	1	3	7	2
18.	Orthopaedics	1	-	3	-
19.	Ophthalmology	1	-	1	-
20.	OT	-	-	6	-
21.	Pathology	-	-	2	-
22.	Paediatrics	3	-	6	1
23.	Paediatrics Surgery	-	-	-	1
24.	Psychiatry	-	-	-	4
25.	PSM	-	-	2	12
26.	Pharmacology & Therapeutics	-	-	-	2
27.	Physiology	-	-	1	4
28.	PT	-	-	5	-
29.	Radiology	-	-	2	-
30.	Transfusion Medicine	-	1	1	-
31.	Urology	-	-	-	3
	<b>TOTAL Reviewed</b>	<b>35</b>	<b>10</b>	<b>52</b>	<b>49</b>

	<b>Serious Adverse Event Reports</b>		<b>PHARMA</b>	<b>GOVT</b>	<b>OA</b>	<b>Thesis</b>
1	Total no. of SAE at our site	Initial report	10	-	-	-
		Follow up report	19	-	-	-
2	Total no. of death		3	-	-	-
3	Our site late reporting (after 7 <sup>th</sup> day)			-	-	-
4	Responses from IEC regarding SAE	Query letters sent	54	-	-	-
		Noted letters sent	213	-	-	-
5	SUSAR reviewed		5356	-	-	-
6	AE reports reviewed		4			

**Status of the ongoing sponsored projects of IEC-I as on 31<sup>st</sup> December 2013**

1 project submitted in 1999 is ongoing.  
1 project submitted in the Year 2001 is ongoing.  
3 out of 59 projects submitted in the Year 2004 are ongoing  
1 out of 52 projects submitted in the Year 2005 are ongoing  
2 out of 69 projects submitted in the Year 2007 are ongoing  
3 out of 45 projects submitted in the Year 2008 are ongoing  
6 out of 47 projects submitted in the Year 2009 are ongoing  
9 out of 51 projects submitted in the Year 2010 are ongoing  
23 out of 51 projects submitted in the Year 2011 are ongoing  
16 out of 38 projects submitted in the Year 2012 are ongoing

**Status of the ongoing academic projects of IEC-I as on 31<sup>st</sup> December 2013**

15 out of 15 thesis and 5 out of 5 other academic projects submitted in the year 2012 are ongoing.

**Constitution of the IEC-I as on 31<sup>st</sup> December 2013**

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

	<b>Name</b>	<b>Position on IEC I</b>	<b>Designation &amp; Affiliation</b>	<b>Qualification</b>	<b>Gender</b>
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. Sunil Karande	Member	Professor (Paediatrics)GSMC & KEMH	M.D., DCH, DIT, FIAP	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	MPT	F
<b>Alternate Members of IEC-I</b>					
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 &	B.Sc., L.L.B., Dip in Medical Jurisprudence and forensic science.	M

			others)		
4	Mrs. Sharmila Kher	Alternate Member (External Layperson)	-	M. SC. Part 1 (Biotechnical science), Dip. In Journalism, PGDHA	F
5	Mrs. SameenaMaldar	Alternate Member (External Layperson)	-	S.Y.B.A.	F
6	Ms. NiveditaChalill	Alternate Member (External Social Scientist)		M.A., Ph.D., M.Phill 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

### Activities of the IEC-II in the year 2013

Year 2011	Total reviewed projects	Under Process	Approved	Rejected	Terminated
PHARMA	6	6	-	-	-
GOVT	3	1	2	-	-
Thesis	125	24	96	1	4
Other Academic	99	58	39	2	-
<b>Total</b>	<b>233</b>	<b>89</b>	<b>137</b>	<b>3</b>	<b>4</b>

### **Status of the ongoing academic projects as on 31<sup>st</sup> December 2012**

4 Thesis projects submitted in the Year 2007 are ongoing.  
11 out of 233 Thesis and 4 out of 119 other academic projects submitted in the Year 2008 are ongoing.  
4 out of 209 thesis and 56 out of 96 other academic projects submitted in the Year 2009 are ongoing.  
39 out of 173 thesis and 84 out of 119 other academic projects submitted in the year 2010 are ongoing.  
106 out of 214 thesis and 70 out of 86 other academic projects submitted in the year 2011 are ongoing.  
221out of 234 thesis and 78 out of 87 other academic projects submitted in the year 2012 are ongoing.

Year 2013		PHARMA	GOVT
<b>I</b>	<b>Total no. of projects reviewed</b>	<b>8</b>	<b>5</b>
<b>II</b>	<b>Total ongoing projects</b>	<b>-</b>	<b>2</b>
<b>III</b>	<b>Type of study</b>	Phase I	
		Phase II	1
		Phase III	4
		Phase IV	-
		NA	3

	Departments	PHARMA	GOVT	Thesis	Other Academic
1.	Anatomy	-	-	1	-
2.	Anaesthesia	-	-	19	2
3.	Biochemistry	-	-	2	1
4.	Cardiology	1	-	-	3
5.	Clinical Pharmacology	-	2	2	6
6.	Chest Medicine	-	1	3	1
7.	Dermatology	-	-	1	1
8.	Endocrinology	-	1	1	4
9.	ENT	-	-	7	-
10.	Forensic Medicine	-	-	-	1
11.	Gastroenterology	3	-	-	5
12.	General Surgery	-	-	7	-
13.	Infection diseases	-	-	-	1
14.	Medicine	-	-	13	3
15.	Microbiology	-	-	4	7
16.	Neurology	1	-	-	1
17.	Neurosurgery	-	-	-	2
18.	Nephrology	-	-	2	-
19.	Neonatology	-	-	-	6
20.	Obstetrics and Gynaecology	1	1	11	4
21.	Orthopaedics	-	-	9	4
22.	Ophthalmology	1	-	1	-
23.	OT	-	-	1	2
24.	Pathology	-	-	4	1
25.	Paediatrics	1	-	3	3
26.	Paediatrics Surgery	-	-	-	1
27.	Plastic Surgery	-	-	-	1
28.	Psychiatry	-	-	4	5
29.	PSM	-	-	16	13
30.	Pharmacology & Therapeutics	-	-	3	9
31.	Physiology	-	-	2	5
32.	PT	-	-	5	3
33.	Radiology	-	-	1	1
34.	Transfusion Medicine	-	-	1	-
35.	Urology	-	-	-	4
	<b>Total Reviewed</b>	<b>8</b>	<b>5</b>	<b>125</b>	<b>99</b>

**Constitution of IEC-II**

	<b>Name</b>	<b>Position on IEC II</b>	<b>Designation &amp; Affiliation</b>	<b>Qualification</b>	<b>Gender</b>
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 Expert)	legal	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

				M.A.(Clinical Psychology), N.E.T in Psychology, PGDIP., Dip TD.	
<b>Alternate Members of IEC-I &amp; II</b>					
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 Chalil	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 ( <a href="mailto:nayanvkatkar@gmail.com">nayanvkatkar@gmail.com</a> ) 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
<b>Contact details:</b> Email: <a href="mailto:iec-1@kem.edu">iec-1@kem.edu</a> , <a href="mailto:iec-2@kem.edu">iec-2@kem.edu</a> , Direct no.:24122188	



## Significant achievements and activities of the IEC-I & II in the year 2013

### 1. Training programs organized by IECs:

- a) Organized a one day workshop for IEC members and staff on 11<sup>th</sup> October 2013 by the IEC at MET Cell, Seth GSMC & KEMH.
- b) Organized half day Workshop on “Good Clinical Practice” for IEC members on 6<sup>th</sup> March 2013 at Seminar Hall of Dept. of Clinical Pharmacology of Seth G. S. Medical College and K. E. M. Hospital, Mumbai, Maharashtra.

### 2. Training programs attended by CARE members and staff for updating GCP training Participation of members:

- a) 2<sup>nd</sup> FERCI National conference on Bioethics and Clinical Research Regulations Organized by FERCI at PSG Institute of Medical Sciences and Research, Coimbatore attended by Dr. UM Thatte, Dr. Kamal Hazari, Dr. Raakhi Tripathi, Dr. Shruti Bhide, Dr. Sharmila Jalgaonkar, Dr. YC Shetty, Dr. S. Salgoankar, and Mrs. Janhavi Katkar.
- b) All members of IEC-I & II attended a one day workshop organized by IEC for its members and staff on 11<sup>th</sup> October 2013 at MET Cell, Seth GSMC & KEMH.

### 4. 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. Jahnvi Katkar, Dr. UM Thatte Presented at 2nd National Conference of FERCI 2013 held at PSG Coimbatore

### b) Presented posters related to research ethics at conferences:

1. Impact of recent regulatory guidelines on the functioning of Ethics Committee at a tertiary care Institute in Mumbai. **Dr. SS Bhide**, Dr. SV Jalgaonkar, Dr. RK Tripathi, Dr. YC Shetty, Dr. PA Marathe, Mrs. Janhavi Katkar, Dr. UM Thatte Presented at 2nd National Conference of FERCI 2013 held at PSG Coimbatore.
2. "Informed consent for Anaesthesia in clinical practice" - poster Presented at 2nd National Conference of FERCI 2013 held at PSG Coimbatore, **Dr. Sweta Salgaonkar**.
3. "Queries raised by the Institutional Ethics Committee(IEC) of a tertiary care hospital in Mumbai – a ten year analyses" poster Presented at 2nd National Conference of FERCI 2013 held at PSG Coimbatore, by **Dr. YC Shetty**, Dr. SK Kamat, Dr. PA Marathe, Dr. SB Raut.

### 5. Publication related to research ethics in scientific journals

**Dr. Vikram Londhey** (Co-Chairperson, IEC-I)“Awareness about Ethics committees amongst medical teachers in a medical college” submitted for publication in JAPI No. 321/2013 under peer review.

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

a) **Dr. Vikram Londhey** (Co-Chairperson, IEC-I) “Awareness about Ethics committees amongst medical teachers in a medical college” presented at APICON 2013 at Coimbatore received the JN Berry Award for the Oral Presentation.

b) **Dr. Vikram Londhey** (Co-Chairperson, IEC-I) received the second prize for the Senior Category for this paper in staff Society Presentation at Nair Hospital in 2012-2013.

3. **Dr. YC Shetty** (Member, IEC-II) received a best poster award on “Queries raised by the Institutional Ethics Committee(IEC) of a tertiary care hospital in Mumbai – a ten year analyses” at 2nd National Conference of FERCI 2013 held at PSG Coimbatore.

**Dr. Shruti Bhide**  
**Member Secretary**  
**IEC-I**

**Dr. Sharmila Jalgaonkar**  
**Member Secretary**  
**IEC-II**