

INSTITUTIONAL REVIEW BOARD (IRB)
1] IRB (I)
Ethics Committee for Research on Human Subjects (ECRHS)
 Established: 1986
2] IRB (II)
Committee for Academic Research Ethics (CARE)
 Established: Nov 2008
 Current SOPs Version 3.1: 1st August 2012

Received the SIDCER re-recognition award for compliance to international standards in Nov 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 ECRHS in the year 2012

A total of **thirty one meetings (11 full board meetings, 1 SOP training meeting and 19 SAE Subcommittee meetings)** were held in the year 2012. A total of 32 pharmaceutical sponsored projects and 9 government sponsored projects were submitted to the Ethics Committee 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 ECRHS members, pertaining to modifications in the protocol were sent to investigators. The answers to ECRHS comments were then reviewed and the project was granted approval. Till date 12 projects out of 41 projects have been approved, 3 projects have been archived due to termination by the sponsor and for the remaining 26, replies are awaited.

	Year 2011	PHARMA	GOVT
I	Total no. of projects reviewed	32	9
II	Total ongoing projects	12	2
III	Type of study		
	Phase I	-	-
	Phase II	7	-
	Phase III	15	-
	Phase IV	4	-
	NA	2	9
	Proof of concept	1	-
	Prospective observational	1	-
	Observational	1	-
	Regulatory premarket medical device study	1	-
IV	Departments	PHARMA	GOVT
1.	Cardiology	4	-
2.	Clinical Pharmacology	-	2
3.	Endocrinology	10	-

4.	Dermatology	1	-	
5.	Gastroenterology	4	-	
6.	General Surgery	1	-	
7.	Heamatology	1	-	
8.	Medicine	2	-	
9.	Microbiology	-	1	
10.	Neurology	2		
11.	Neurosurgery	-	2	
12.	Nephrology	-	1	
13.	Obstetrics and Gynaecology	1	1	
14.	Orthopaedics	1	-	
15.	Ophthalmology	1	-	
16.	Paediatrics	1	-	
17.	Plastic Surgery	1	-	
18.	Psychiatry	2	1	
19.	Urology	-	1	
	Serious Adverse Event Reports	PHARMA	GOVT	
1	Total no. of SAE at our site:	a) Initial report b) Follow up report	28 22	-
2	Total no. of death		3	-
3	Our site late reporting (after 7 th day)		-	-
4	Responses (query)from EC regarding SAE	Query letters	44	-
		Noted letters	52	-
5	SUSAR		12,163	-

Status of the ongoing sponsored projects as on 31st December 2011

1 project submitted in 1999 is ongoing.
1 project submitted in the Year 2001 is ongoing.
4 out of 59 projects submitted in the Year 2004 are ongoing
1 out of 52 projects submitted in the Year 2005 are ongoing
4 out of 69 projects submitted in the Year 2007 are ongoing
7 out of 45 projects submitted in the Year 2008 are ongoing
7 out of 47 projects submitted in the Year 2009 are ongoing
15 out of 51 projects submitted in the Year 2010 are ongoing
33 out of 51 projects submitted in the Year 2011 are ongoing

Constitution of the ECRHS as on 31st December 2012

Name of Members	Position on Ethics Committee	Designation & Affiliation	Qualification	Gender
1. Dr. Manu Kothari	Chairperson (External)	-	M.S., M. SC. (Anatomy)	M
2. Dr. Sunil Kuyare	Member secretary	Assistant Professor,	M.D., DHA, FME.	M

		(Microbiology) GSMC & KEMH		
3. Dr. Sandeep Bavdekar	Member (External Scientific Expert)	Professor and Head (Pediatrics) TN Medical College and BYL Nair Hospital.	M.D., D.C.H.	M
4. Dr. Smrati Bajpai	Member,	Assistant Professor, (Medicine) GSMC & KEMH	M.D., DNB.	F
5. Dr. Kaizad Damania	Member (External Scientific Expert)	Professor (Obstetrics & Gynaecology) N. Wadia Maternity Hospital	M. D., DNB., F.C.P.S., D.G.O., D.F.P.	M
6. Mrs. Manisha Naik Dalal	Member (External Layperson)	-	M.Com	F
7. Dr. (Mrs.) Helen Joseph	Member (External Social Worker)	Faculty Member College of Social Work of Nirmala Niketan Institute	M.S.W., M. Phil., Ph.D.	F
8. Dr. Sandhya Kamat	Member	Professor (Pharmacology & Therapeutics) GSMC & KEMH	M.D.	F
9. Dr. Padmaja Marathe	Member	Professor (Additional) (Pharmacology & Therapeutics) GSMC & KEMH	M.D.	F
10. Dr. Milind Y. Nadkar	Member	Professor, (Medicine) GSMC & KEMH	M.D., FICP	M
11. Dr. Sweta Salgaonkar	Member	Professor, (Anesthesiology) GSMC & KEMH	M.D.	F
12. Dr. Yashashri Shetty	Member	Assistant Professor, (Pharmacology & Therapeutics) GSMC & KEMH	M.D., DBM.	F
13. Dr. Subodh Sirur	Member (External Legal Expert)	Consultant, Dermatology & Venereology, Mahatma Gandhi Memorial Hospital, Mumbai.	MBBS, DVD, LLM	M
14. Dr. Avinash Supe	Member	Professor & Head (Surgical Gastroenterology) GSMC & KEMH	M.S., FCPS, FICS, DME, DNBE, DHA.	M
15. Dr. Urmila Thatte	Member	Professor & Head (Clinical Pharmacology) GSMC & KEMH	M.D., DNB., Ph.D.	F
Alternate Members				
1. Dr. Pradnya Talawadekar	Alternate Member (External Legal Expert)	Project Manager, Ojus Medical Institute, The Tulip Star, Juhu Tara Road Juhu, Mumbai 400049	B.A.M.S., L.L.M.	F
2. Mrs. Sadhana Bhatkhande	Alternate Member (Social Worker)	Medical Social Worker, (Psychiatry) GSMC & KEMH	M.A. (in social work), Masters in counseling and Psychotherapy.	F
3. Mrs. Sharmila Kher	Alternate Member (External Layperson)	-	M. SC. Part 1 (Biotechnical science), Dip. In Journalism, PGDHA	F
Co-opted Member				
1. Dr. Raakhi Tripathi	Co-opted Member (Secretary, SAE-Subcommittee of the ECRHS)	Associate Professor, (Pharmacology & Therapeutics) GSMC & KEMH	M.D.	F

Activities of the CARE in the year 2012

A total of **ten full board meetings** were held in the year 2012. 3 projects were approved at first submission as there were no scientific and ethical issues in the submitted protocols.

Year 2012	Total reviewed projects	Under Process	Approved	Rejected
Thesis	249	80	166	3
Other Academic	92	24	68	-

Departments	Thesis	Other Academic
Anatomy	8	1
Anaesthesia	26	5
Chest Medicine	4	-
Dental	-	1
ENT	1	-
Pharmacology	1	3
Orthopedics	11	3
Medicine	23	2
Neurology	2	1
Nursing	1	4
Nephrology	2	1
Neuro surgery	-	1
Neonatology	-	1
Ophthalmology	3	-
Occupational Therapy	7	5
Physiotherapy	30	3
Pathology	13	1
Physiology	6	13
Transfusion Medicine	2	1
PSM	20	6
Paediatrics	11	2
Psychiatry	8	6
Radiology	3	0
Microbiology	6	11
Cardiology	-	3
Surgery	14	-
Gastroenterology	3	3
Surgical Gastroenterology	5	-
Nuclear Medicine	2	-
Pediatric Surgery	1	1
Plastic Surgery	-	1
Endocrinology	2	3
Obstetrics and Gynecology	27	2
Clinical Pharmacology	2	4
Hematology	-	-
Dermatology	4	1
Paediatrics Neurology	1	-
HIP Surgery	-	1
Immunoematology	-	1

Status of the ongoing academic projects as on 31st 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.

141 out of 214 thesis and 66 out of 86 other academic projects submitted in the year 2011 are ongoing.

Constitution of CARE

Sr. no.	Name of Members	Position on Ethics Committee	Designation & Affiliation	Qualification	Gender
1	Dr. Kamal Hazari	Chairperson (External)	(Former Sr. Deputy Director - NIRRH – ICMR (Mumbai))	M.D,D.G.O, DFP	F
2	Dr. Yashashri Shetty	Member Secretary	Assistant Professor, (Pharmacology & Therapeutics) GSMC & KEMH	M.D., DBM.	F
3	Dr. Anahita Chauhan	Member	Assoc. Professor, (Obstetrics & Gynecology) GSMC & KEMH	M.D.	F
4	Dr. Sona Dave	Member (External Scientific Member)	Professor, (Anesthesiology) TYBL & Nair Hospital	M.D., DNB	F
5	Dr. Shilpa Adarkar	Member	Assistant Professor, (Psychiatry) GSMC & KEMH	M.D.	F
6	Dr. Vikram Londhey	Member (External Scientific Expert)	Associate Professor (Medicine & Rheumatology clinic) TNMC & BYL Nair Charitable Hospital	M.D.	M
7	Mrs. Manju Manda	Member (External Layperson)	Section officer Railways	B.Sc. Pharmacy	F
8	Dr. Mohan Desai	Member	Professor (Orthopedics) Seth GSMC & KEMH	M.S, MCPS	M
9	Dr. Aparna Deshpande	Member	Professor, (Surgery) Seth GSMC and KEMH	M.S, D.N.B.E F.I.A.G.E.E.S	F
10	Mrs. Punita V. Solanki	Member	Assistant Professor, (Occupational Therapy) Seth GSMC and KEMH	MSc (O.T.)	F

11	Dr. Mouleshri Vyas	Member, (External Social Scientist)	Associate Professor & Chairperson, COPD, SSW, TISS	Ph.D. Sociology	F
12	Mrs. Sushma Singh.	(External legal Expert)	Member	B. Pharm. LL.B. LL.M Certificate in Alternative Disputes Resolution (ADR)	F
Alternate members					
1	Mrs. Sadhana Bhatkhande	Alternate Member (Social Worker)	Medical Social Worker,(Psychiatry) GSMC & KEMH	M.A. (in social work), Masters in counseling and Psychotherapy.	F
2	Mrs. Sameena Maldar	(Alternate Layperson)	Member	S.Y.B.A.	F
3	Dr. Sadhana Mahashabde	Member (External Alternate Legal Expert)	Advocate High Court	B.Sc., LLB, LLM, PhD.	F

IRBs Office bearers

ECRHS (IRB I)	CARE (IRB II)
Mrs. Janhavi Katkar, Administrative Manager (nayanvkatkar@gmail.com)	
Ms. Manali Vengurlekar, Executive Assistant	Mr. Shyam Tawde, Administrative Officer
Ms. Deepika Paradkar, Executive Assistant	Ms. Bhupali Kore, Executive Assistant
Mr. Mangesh Khochade, Office Attendant	Mr. Naresh Bhawale, Office Attendant
Contact details: Email: ethicscommittee@kem.edu , Intercom no.: 7515 Direct no.: 24122188, 24107515	

Significant achievements and activities of the IRBs in the year 2012

1. Training programs organized by IRBs:

- a) Organized two one day workshops, one for investigators on 12th March 2012 and other for ethics committee members on 13th March 2012 by ASSANSA foundation at MLT, Seth GSMC & KEMH.
- b) Organized One Day Workshop on "Good Clinical Practice" at Seth G. S. Medical College and K. E. M. Hospital, Mumbai, Maharashtra, India 8th May 2012, Tuesday from 8.00 am to 5.30 pm at Jivraj Mehta Lecture Theatre in collaboration with Occupational therapy department.

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

- a) First Maharashtra State Research Ethics Conference Organized by Sancheti Hospital Pune in collaboration with FERCI on 21st July 2012 at Hotel Pride, Pune attended by Dr. YC Shetty, Dr. Kamal Hazali, Dr. S. Salgoankar, Ms. Sushma Singh and Mrs. Janhavi Katkar.
- b) Staff members of the CARE Mrs. Janhavi Katkar, Ms. Padmini Jadhav, Mr. Shyam Tawde and Mr. Kiran Barasker attended workshop on Good Clinical Practice on 8th September 2012 organized by Research Society Seth GSMC and K E M Hospital.

3. Presentation of research ethics related papers at conferences:

- a) Guest lecture taken by Dr. Yashashri Shetty on "ICMR Guidelines for Biomedical research and responsibilities of the investigator" and "Informed Consent Process" at Research Methodology and Biostatistics Workshop for Nair dental College, Bombay Central on 6th – 8th February 2012.
- b) Guest lecture by Dr Yashashri Shetty for the conference "Ethics and Regulations: Expanding horizons & changing dynamics in clinical research" on the topic "Choice of controls: Placebo vs standard care" on 26th February 2012 at Darbar Hall, Haffkine Institute, Parel conducted by MUHS Infectious Disease department and MSC Pharmaceutical Sciences .
- c) Guest lecture by Dr Yashashri Shetty on "Evolution of Ethical Guidelines based on Historical Background and Overview of ICMR Ethical Guidelines, ICH-GCP, Indian GCP and Schedule 'Y'" from 9 to 10 am on 8th May 2012 at MLT, Seth GSMC & KEMH conducted by Department of Occupational Therapy.
- d) Dr Yashashri Shetty was a resource person for "Basic Workshop in Research methodology" 3 day workshop at R.A. Podar Medical College (Ayurveda), Worli, Mumbai from 30th July to 1 August 2012 and took lecture on "Selection of Research Topic and Framing a Research Question with Group Exercises".
- e) Dr Yashashri Shetty was a resource person for "Research Methodology and Biostatistics Workshop" A 3 day workshop at MGM Dental College, Navi Mumbai from 3rd October to 5th October 2012 and took lecture on "Clinical Study Designs with emphasis on Avoidance of Bias with Group Exercises".
- f) Dr Yashashri Shetty was a resource person for " Basic Workshop in Research methodology" 3 day workshop at Bombay Hospital college of Nursing ,Bombay Hospital, Nariman Point, Mumbai from 10th Sep to 12th Sept 2012 and took lecture on "Selection of Research Topic and Framing a Research Question with Group Exercises"
- g) Invited Guest lecture by Dr Yashashri Shetty at 175th Staff society meeting held on 27th November 2012 at Sen kinare Auditorium on "KEM Hospital Ethics committees: Experience sharing".
- h) Dr Yashashri Shetty was invited to conduct a session on "**Ethical Requirement and Issues**". In "**Research Methodology Workshop**" from 12th to 14th December 2012 conducted by Medical Education Unit of Seth GSMC & KEM Hospital, Parel, Mumbai.

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

- 1) Dr. Patil AE, Kamat SK, Marathe PA, Shetty YC, Kuyare SS. Participation of Normal volunteers in clinical Research: An overview of Ethical issues. This paper was presented at **Maharashtra Pharmacologist's Conference 2012 on 13th -14th July 2012.**
- 2) Kuyare S, Kamat SK, Marathe PA, Shetty YC, Thatte UM, Katkar JV Retrospective Analysis of Outcomes/Decisions Related to Revision of Proposals Submitted to an Institutional Review Board Seth G. S. Medical College & K.E.M. Hospital Ethics Committee, Mumbai, India has been published in Booklet titled "12th FERCAP International Conference & General Assembly ,Development, Ethnicity, Culture and Ethical Health Research, Resource Material version 2 , November 18-21, 2012, Water edge , Colombo, Sri Lanka, Pg. 132.

b) Presented posters related to research ethics at conferences:

- 1) Katkar JV, Shetty YC, Kuyare SS, Marathe PA, Kamat SK, Thatte UM made a poster presentation about "Activities of the IRB" during the 12th Annual International Conference of the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP) held at Waters Edge Convention Center, Colombo,Sri Lanka on November 18-21, 2012.

5. Publication related to research ethics in scientific journals

- a) Shetty YC¹, Marathe PA², Kamat SK³, Thatte UM⁴ Continuing Oversight through Site Monitoring: experiences of an institutional ethics committee in an Indian tertiary -care hospital. Indian Journal of Medical Ethics. Jan 2012; IX(1):22-26.
- b) Shetty YC, Marathe PA, Billa GV, Nambiar N. A study to assess completeness of project application forms submitted to institutional ethics committee (IEC) of a tertiary care hospital. Perspectives in Clinical Research. Oct-Dec 2012; 3(4): 133-38.
- c) Dr. Patil AE, Kamat SK, Marathe PA, Shetty YC, Kuyare SS. Participation of Normal volunteers in clinical Research: An overview of Ethical issues. Booklet of Maharashtra Pharmacologist's Conference 2012. **13th-14th July 2012: 20-21.**

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

- a) Mrs. Janhavi Katkar received a 'Best poster presentation award' about "Activities of the IRB" during the 12th Annual International Conference of the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP) held at Waters Edge Convention Center, Colombo, Sri Lanka on November 18-21, 2012.

7. Assistance provided to other Ethics Committees:

The IRBs have assisted many other ethics committees for setting up and formation of SOPs within and outside Mumbai like Ethics committee of Seven Hills hospital Mumbai, Shatabdi Hospital Naskhik, Asha Parekh Hospital of SantaCruz, Mumbai, and Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow. Few members from these committees have undergone Hands-on training as observers and got trained in the IRBs office and during the IRBs meetings.

Dr. Shruti Bhide
Member Secretary
IRB-I

Dr. Sharmila Jalgaonkar
Member Secretary
IRB-II