

Annual Report of the year 2010
Ethics Committee for Research on Human Subjects (ECRHS)
Seth GS Medical College and KEM Hospital

Established: 1986

Reformulated in 1999 with the chairperson from outside the institution
Received the SIDCER recognition award for compliance to international standards in
Nov 2009

First version of SOPs: May 2000
 Second version of SOPs: Nov 2005
 SOPs dated: 14th November 2008
 Third version of SOPs: 26th June 2009

The committee presently functions according to the requirements laid down in Schedule Y (20th January 2005) 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 2010

A total of **eleven meetings were held in the year 2010**. A total of 43 pharmaceutical sponsored projects and 8 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 17 projects out of 51 projects have been approved, and for the remaining 34, replies are awaited.

Year 2010		PHARMA	GOVT
I	Total no. of projects reviewed	43	8
II	Total ongoing projects	17	3
III	Type of study	Phase I	-
		Phase II	7
		Phase III	23
		Phase IV	7
		Pre-clinical research	1
		Surveillance	1
		NA	4
IV	Departments	PHARMA	GOVT
1.	Pharmacology	3	-
2.	Orthopaedics	1	-

3.	Medicine	4 (HIV - 1)	
4.	Neurology	6	-
5.	Paediatrics	1	-
6.	Psychiatry	-	1
7.	Microbiology	2	2
8.	Cardiology	3	-
9.	Surgery	3	-
10.	Urology	1	-
11.	Gastroenterology	4	-
12.	Nuclear Medicine	-	1
13.	Dentistry	1	-
14.	Plastic Surgery	1	-
15.	Endocrinology	5	-
16.	Gynaecology	1	4
17.	Clinical Pharmacology	1	-
18.	Haematology	2	-
19.	Dermatology	4	-
	Serious Adverse Event Reports	PHARMA	GOVT
1	Total no. of SAE at our site	58	2
2	Total no. of death	14	1
3	Our site late reporting (after 7 th day)	4	-
4	Responses (query)from EC regarding SAE	Query letters	18
		Noted letters	40
5	SUSAR	1580	-

Status of the ongoing sponsored projects as on 31st January 2010

1 project submitted in 1999 is ongoing.

2 projects submitted in the Year 2001 are ongoing.

1 project submitted in the Year 2002 is ongoing

5 out of 59 projects submitted in the Year 2004 are ongoing

3 out of 52 projects submitted in the Year 2005 are ongoing

6 out of 64 projects submitted in the Year 2006 are ongoing

12 out of 69 projects submitted in the Year 2007 are ongoing

17 out of 45 projects submitted in the Year 2008 are ongoing

25 out of 47 projects submitted in the Year 2009 are ongoing

Significant achievements and activities of the ECRHS in the year 2010

1. Three members of the ECRHS Dr. Urmila Thatte, Dr. Padmaja Marathe and Dr. Yashashri Shetty contributed as faculty in 1st National Workshop on Ethics conducted by FERCI in collaboration with Tata Memorial Centre Human Ethics Committee (TMCHEC)

and Pfizer Ltd on Wednesday, 6th October 2010 at GJ Auditorium, Tata Memorial Hospital, Parel, Mumbai.

2. Dr. Yashashri Shetty presented a paper on “Providing Continuing Oversight for Ethical Health Research” presented at 10th annual international conference by the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP) at the Equatorial Shanghai Hotel in Shanghai, China on November 22-25, 2010 and a paper entitled “Promotion of ethical health research by continuing oversight through site monitoring- Experience of an Institutional Ethics Committee in a tertiary care hospital in India” in UK SHETH Prize Paper Session held on 14th December 2010 at the 43rd Annual Conference of Indian Pharmacological Society (IPS) and International Conference on “Pharmacology & Translational Research at National Institute of Nutrition, Hyderabad.
3. Dr. Sunil Kuyare one of the ECRHS member, attended the workshop on ‘Ethics Review of Clinical Research: A phase I training conference for research ethics committee members’ at Hyderabad, India on 19th & 20th July 2010.
4. Dr. Sweta Salgoankar ECRHS member attended the workshop on ‘DAIDS Regional Training Event’ at Pune, India on 10–15 May 2010. The theme of the workshop was US– India partners in protection: addressing regulatory challenges in 2010.

Constitution of the ECRHS from 1st January 2011

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, (Microbiology) GSMC & KEMH	M.D., DHA, FME.	M
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. 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
5. Mrs. Manisha Naik Dalal	Member (External Layperson)	-	M.Com	F

6. 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
7. Dr. Sandhya Kamat	Member	Professor (Pharmacology & Therapeutics) GSMC & KEMH	M.D.	F
8. Dr. Padmaja Marathe	Member	Associate Professor (Pharmacology & Therapeutics) GSMC & KEMH	M.D.	F
9. Dr. Milind Y. Nadkar	Member	Professor, (Medicine) GSMC & KEMH	M.D., FICP	M
10. Dr. Sweta Salgaonkar	Member	Associate Professor, (Anesthesiology) GSMC & KEMH	M.D.	F
11. Dr. Yashashri Shetty	Member	Assistant Professor, (Pharmacology & Therapeutics) GSMC & KEMH	M.D., DBM.	F
12. Dr. Avinash Supe	Member	Professor & Head (Surgical Gastroenterology) GSMC & KEMH	M.S., FCPS, FICS, DME, DNBE, DHA.	M
13. Dr. Urmila Thatte	Member	Professor & Head (Clinical Pharmacology) GSMC & KEMH	M.D., DNB., Ph.D.	F
14. Dr. D. N. Upasani	Member (External Legal Expert)	Medical Director, Ghatkopar Hindusabha Hospital Mumbai	M.S., L.L.B.	M
15. Dr. Raakhi Tripathi	Co-opted Member	Associate Professor, (Pharmacology & Therapeutics) GSMC & KEMH	M.D.	F
16. Mrs. Sadhana Bhatkhande	Alternate Member (Social Worker)	Medical Social Worker, (Psychiatry) GSMC & KEMH	M.A. (in social work), Masters in counseling and Psychotherapy.	F
17. Mrs. Pratibha Rao	Alternate Member (External Layperson)	-	M. SC. (Chemistry)	F
18. Mrs. 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

