

Date: 3rd January 2012

Annual Report of the year 2011

**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 2011

A total of **twenty five meetings (11 full board meetings, 1 SOP training meeting and 1 emergency meeting)** were held in the year 2011. A total of 42 pharmaceutical sponsored projects and 10 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 Till date 14 projects out of 52 projects have been approved, 4 projects have been archived due to termination by the sponsor and for the remaining 32, replies are awaited.

Year 2011		PHARMA	GOVT	
I	Total no. of projects reviewed	42	10	
II	Total ongoing projects	11	5	
III	Type of study	Phase I	1	-
		Phase II	5	-
		Phase III	17	1
		Phase IV	7	1
		NA	12	8
IV	Departments	PHARMA	GOVT	
1.	Biochemistry	-	1	
2.	Cardiology	4	-	
3.	Chest Medicine	1	1	

4.	Clinical Pharmacology	8	-
5.	Endocrinology	3	1
6.	Gastroenterology	2	-
7.	Immunohaematology	1	1
8.	Medicine	5	-
9.	Microbiology	-	1
10.	Neurology	3	-
11.	Neonatology	1	-
12.	Nephrology	1	
13.	Obstetrics and Gynaecology	2	2
14.	Orthopaedics	2	-
15.	Pathology	1	-
16.	Pharmacology	3	-
17.	Psychiatry	-	1
18.	Surgical Gastroenterology	2	-
19.	Urology	3	-
	Serious Adverse Event Reports	PHARMA	GOVT
1	Total no. of SAE at our site	Initial report 27	-
		Follow up report 25	
2	Total no. of death	1	-
3	Our site late reporting (after 7 th day)	-	-
4	Responses (query)from EC regarding SAE	Query letters	24
		Noted letters	58
5	SUSAR	11,579	-

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.
5 out of 59 projects submitted in the Year 2004 are ongoing
2 out of 52 projects submitted in the Year 2005 are ongoing
3 out of 64 projects submitted in the Year 2006 are ongoing
9 out of 69 projects submitted in the Year 2007 are ongoing
15 out of 45 projects submitted in the Year 2008 are ongoing
20 out of 47 projects submitted in the Year 2009 are ongoing
31 out of 51 projects submitted in the Year 2010 are ongoing

Significant achievements and activities of the ECRHS in the year 2011

1. **Training programs organized by the ECRHS:** First FERCI National Conference on Research Ethics: Challenges for Ethics Committees on 5th - 6th Nov, 2011 in India was organized by Tata Memorial Hospital, in Association with, K E M Hospital Mumbai.
2. **Training programs attended by ECRHS members and staff for updating GCP training Participation of members :**
 - a. Seven members of the the ECRHS Dr. Urmila Thatte, Dr. Sandeep Bavdekar, Dr. Sunil Kuyare, Dr. Padmaja Marathe, Dr. Yashashri Shetty, Dr. A. N. Supe, Mrs. Manisha Naik Dalal and two staff members of the ECRHS Mrs. Janhavi Katkar and Ms. Padmini Jadhav attended the first FERCI National Conference on Research Ethics: Challenges for Ethics Committees on 5th - 6th Nov, 2011
 - b. Two staff members of the ECRHS Mrs. Janhavi Katkar and Ms. Padmini Jadhav attended workshop on Statistics and Research Methodology on 27th - 28th Sep, 2011, Organized by Research Society Seth GSMC and K E M Hospital.
 - c. CITI Course in The Protection of Human Research Subjects: Dr. Bavdekar has completed an online training course in Ethics and is ongoing for Dr. Urmila Thatte, Dr. Padmaja Marathe, Dr. Sunil Kuyare and Mrs Janhavi Katkar
3. **Presentation of research ethics related papers at conferneces :**
 - a. Dr. Padmaja Marathe, Dr. Yashashri Shetty and Dr. Sweta Salgoankar were invited as Faculty for the lecture on “ Role and responsibilities of EC”, “History of Research Fraud and evolution of Ethics Hospital Ethics Committee” and “Challenges before Ethics Committee” for the first training programme for members of Committees by Shatabdi Ethics Committee- “Shatabdi EC-CON 2011” . It was held at the Opal Hall of Hotel Emerald Park on Sunday February 27th 2011 at Nashik.
 - b. “Shatabdi EC-CON 2011” activity along with the faculty name appeared in different newspaper like Desh – Dhoot, Gaokari, Navakaal, Loksatta and Lokmat on 27th and 28th February 2011.
 - c. Dr. Yashashri Shetty was invited as Faculty for the guest lecture on “Formation of Ethics committee Role and responsibilities of EC for C.L.A.I.M.S Pvt Ltd at Hindustan Polymides & Fibres Ltd. Unit 1004, B Wing, 10th Floor, Peninsula Tower, Peninsula Corporate Park , Lower Parel (W), Mumbai: 400 013 on 8th August 2011 from 2.30 till 4.30 p.m.
4. **Presented papers related to research ethics at conferences:**
 - a. Shetty YC, Marathe PA, Billa.GV, Nambiar. N on “A Study Of Application Forms Submitted to the Ethics Committee” at 1st FERCI National conference on Research Ethics on 6th November 2011 at TMH, Parel ,Mumbai.
 - b. Shetty YC, Marathe PA, Kamat SK, Thatte UM. Promotion of Ethical Health Research by Continuing Oversight through Site Monitoring – Experiences of the Institutional Ethics Committee in a Tertiary Care Hospital in India. Accepted for publication in Indian Journal of Medical Ethics

5. Publication related to research ethics in scientific journals

- a. Taur SR, Bavdekar SB, Thatte UM. Survey of Ethics Committee protocol approval letters: Compliance with Schedule Y/ ICMR Guidelines 2006. *Indian J Med Ethics 2011; 8(4):214-6

- 6. Winning Prizes for papers related to research ethics at conferences:** Won 1st prize for the paper presented by Marathe PA*, Tripathi RK, Kamat SK, Shetty YC, Kuyare SS, Thatte UM. Compensation for Participation in Research: A Review of Protocols and Informed Consent Documents Submitted for Review to two Ethics Committees were presented at 1st FERCI National conference on Research Ethics on 6th November 2011 at TMH, Parel, Mumbai.

- 7. Assistance provided to other Ethics Committees:** The ECRHS has 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 Santa Cruz, 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 ECRHS office and during the ECRHS meetings.

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.WadiaMaternity 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)	M.D.	F

		GSMC & KEMH		
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 Talawadkar	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

ECRHS Office bearers

Name of Employee	Designation & Affiliation	Gender	Contact details
1. Mrs. Janhavi Katkar	Administrative Manager	F	Email: ethicscommittee@kem.edu nayanvkatkar@gmail.com Intercom no.: 7515 Direct no.: 24122188 Mobile no. : 9820757259
2. Ms. Padmini Jadhav	Executive Assistant	F	
3. Mr. Kiran Baraskar	Office Attendant	M	