

**ANNUAL REPORT of  
Ethics Committee for Research on Human Subjects  
(January 2008 –December 2008)**

The Ethics Committee for Research on Human Subjects was established in the year 1986. In June 1999, the committee was reformulated so that the chairperson was no longer the Head of the Institute and the committee was given its present name. The first version of Standard Operating Procedures was drafted in May 2000 followed by the second version which was printed in November 2005. The committee presently functions according to the new SOPs implemented from 14<sup>th</sup> November 2008. The SOPs are based on the requirements laid down in Schedule Y (20<sup>th</sup> January 2005) , the ICH GCP guidelines for Good Clinical Practice, ethical principles set forth in the Declaration of Helsinki (October 2008) and the Ethical Guidelines for Biomedical Research on Human Subjects (2006) laid down by the Indian Council of Medical Research.

**The present constitution of the ECRHS is as follows**

<b>Name of Members</b>	<b>Position on Ethics Committee</b>	<b>Designation &amp; Affiliation</b>	<b>Qualification</b>	<b>Gender</b>
1. Dr. Manu Kothari	Chairperson (External)	Emeritus Professor, (Anatomy)	M.S.,(Anatomy) M. SC.	M
2. Dr. Padmaja Marathe	Member Secretary	Associate Professor (Pharmacology& Therapeutics) GSMC & KEMH	M.D.	F
3. Dr. Sandeep Bavdekar	Member	Professor (Pediatrics) GSMC & KEMH	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. Mrs. Helen Joseph	Member (External Social Worker)	Faculty Member College of Social Work of Nirmala Niketan Institute	M.S.W.	F
7. Dr. Sandhya Kamat	Member	Associate Professor (Pharmacology& Therapeutics) GSMC & KEMH	M.D.	F
8. Ms. Dhvani Mehta	Member (Lay person)	Government Law College, A. Road, Church gate, Mumbai.	Law Student	F
9. Dr. Milind 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	Joint Member Secretary	Lecturer, (Pharmacology&	M.D., DBM.	F

		Therapeutics) GSMC & KEMH		
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

### Thirteen meetings were held in the year 2008.

A total of 34 pharmaceutical sponsored projects and 4 government sponsored projects were submitted to the Ethics Committee for initial review in the year 2008 till date is as follows:

**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 13 projects of the 34 projects submitted to the ECRHS have been approved. 2 rejected and for 19 projects, the ECRHS has not received any communication from the investigators on comments offered on their projects.

Year 2008	Total reviewed projects	Under Process	Approved	Rejected
Pharmaceutical Sponsored	34	19	13	2
Government sponsored	4	-	4	-

### Status of the ongoing projects as on 4th December 2008

- 1 project submitted in 1999 is ongoing.
- 1 project submitted in 2000 is ongoing.
- 4 projects submitted in the Year 2001 are ongoing.
- 1 project submitted in the Year 2002 is ongoing
- 9 out of 59 projects submitted in the Year 2004 are ongoing
- 5 out of 52 projects submitted in the Year 2005 are ongoing
- 13 out of 64 projects submitted in the Year 2006 are ongoing
- 21 out of 69 projects submitted in the Year 2007 are ongoing

### Ongoing academic projects approved by the ECRHS till 14<sup>th</sup> November 2008

#### 1] Status of the ongoing projects as on 4th December 2008

- 1 out of the 142 projects submitted in 2000 is ongoing.
- 4 out of the 141 projects submitted in the Year 2001 are ongoing.
- 1 out of 185 projects submitted in the Year 2003 is ongoing
- 1 out of 135 projects submitted in the Year 2004 is ongoing
- 173 out of 191 projects submitted in the Year 2005 were approved.
- 113 out of 150 projects submitted in the Year 2006 were approved.
- 317 out of 355 projects submitted in the Year 2007 were approved.
- 204 out of 225 projects submitted in the Year 2008 are approved

## Significant activities of the ECRHS in the year 2008

- 1) **Formulation of new Standard Operating Procedures** – The ECRHS has formulated new detailed, individual task based Standard Operating Procedures (21 in numbers) to ensure strict compliance with national and international ethical guidelines and requirement. The Standard Operating Procedures have been implemented with effect from 14<sup>th</sup> November 2008.
- 2) **Acceptance by the ECRHS to participate in the SIDCER recognition program for international accreditation** - The survey originally scheduled during 1<sup>st</sup> December 08 to 7<sup>th</sup> December 08 has been postponed and will be conducted during 16<sup>th</sup> February 2009 to 22<sup>nd</sup> February 2009.
- 3) **The ECRHS organized and conducted one day workshop** for the teaching staff members of the Seth GS Medical College and KEM Hospital in **“Ethics in Clinical Research”** on 3<sup>rd</sup> October 2008.
- 4) **Formulation of a separate committee for review of academic (Thesis) and investigator initiated projects :Committee for Academic Research Ethics (CARE)-**

Following the workshop held for training of staff members with the permission of the Director ME & MH, a separate committee, Committee for Academic Research Ethics (CARE) to oversee ethical review of thesis and investigator initiated projects was constituted and launched its functioning with effect from 14<sup>th</sup> November 2008. The first meeting of the CARE was held on 3<sup>rd</sup> December 2008.

### The Constitution of the CARE is as follows:

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	Lecturer, (Pharmacology& Therapeutics) GSMC & KEMH	M.D., DBM.	F
3.	Dr. Anahita Chauhan	Member	Assoc. Professor, (Obstetrics & Gynaecology) GSMC & KEMH	M.D.	F
4.	Dr. Y. A. Deshmukh	Member (External Scientific Expert)	Professor & Head (Pharmacology) MGM University, Navi Mumbai.	M.D.	M
5.	Dr. Praveen Iyer	Member	Lecturer, (Anatomy) GSMC & KEMH	M.D.	M
6.	Dr. Sandhya Kamat	Member	Associate Professor (Pharmacology& Therapeutics) GSMC & KEMH	M.D.	F
7.	Dr. Janhavi Kedare	Member	Lecturer, (Psychiatry) GSMC & KEMH	M.D.	F
8.	Dr. Varsha Kulkarni	Member	Professor, (Surgery) GSMC & KEMH	M.S.	F
9.	Dr. Vikram Londhye	Member (External Scientific Expert)	Lecturer (Medicine & Rheumatology clinic) TNMC & BYL Nair Charitable Hospital	M.D.	M

10.	Mrs. Manju Manda	Member (External Layperson)	Section officer Railways	BSc Pharmacy	F
11.	Dr. Padmaja Marathe	Member	Associate Professor (Pharmacology & Therapeutics) GSMC & KEMH	M.D.	F
12.	Dr. Ruchi Nanavati	Member	Professor and Head, (Neonatology) GSMC & KEMH	M.D.	F
13.	Dr. Abhijit Raut	Member	Lecturer, (Radiology) GSMC & KEMH	M.D.	M
14.	Dr. S. R. Suryawanshi	Member	Professor & Head Preventive Social Medicine GSMC & KEMH	M.D.	M
15.	Mr. Elvis Thomas	Member (External Social Worker)	Faculty Member College of Social Work of Nirmala Niketan Institute	M.S.W.	M
16.	Dr. D. N. Upasani	Member (External Legal Expert)	Medical Director, Ghatkopar Hindusabha Hospital Mumbai	M.S., L.L.B.	M

The first meeting of the CARE was held on 3<sup>rd</sup> December 2008. The total number of projects reviewed were 36. There were 23 thesis / dissertation and 13 investigator initiated studies. One investigator initiated study was approved on initial review.