

## **Annual Report of the Year 2009**

### **Ethics Committee for Research on Human Subjects**

**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: 14<sup>th</sup> November 2008

Third version of SOPs: 26<sup>th</sup> June 2009

The committee presently functions according to the requirements laid down in Schedule Y (20<sup>th</sup> 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 2009**

A total of **thirteen meetings were held in the year 2009**. A total of 30 pharmaceutical sponsored projects and 14 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 25 projects out of 44 projects have been approved, and for the remaining 19, replies are awaited.

### **Status of the ongoing sponsored projects**

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

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

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

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

### **Status of the ongoing academic projects**

1 out of the 142 projects submitted in 2000 is 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

1 out of 103 thesis and 2 out of 78 other academic projects submitted in the Year 2005 are ongoing.

1 out of 78 thesis and 3 out of 72 other academic projects submitted in the Year 2006 are ongoing.

34 out of 275 thesis and 14 out of 80 other academic projects submitted in the Year 2007 are ongoing.

116 out of 233 thesis and 80 out of 117 other academic projects submitted in the Year 2008 are ongoing

### **Significant achievements and activities of the ECRHS in the year 2009**

1) **Formulation of new Standard Operating Procedures (SOPs)** – The ECRHS has revised the existing SOPs and added 2 new SOPs on ‘Request for Waiver of Written Informed Consent’ and ‘Exemption from the Ethics Review for Research Projects’ making a total of 23 SOPs. A new Informed Consent Document for research study involving genetic testing was added to SOP 5. The revised SOPs have been implemented with effect from 26<sup>th</sup> June 2009.

2) **Awards – SIDCER Recognition** - It is the matter of pride for us that the ECRHS is the first in the country to be recognized by SIDCER which is “Strategic Initiative for Development of Capacity in Ethical Review”: a network of ethical fora of many countries. The recognition program was organized by the FERCAP (Forum for Ethical Review Committees of Asia-Pacific) and coordinated by the ICMR.

The ECRHS participated in a rigorous **International Survey** held during February 2009 prior to which the members underwent a series of trainings (following 3 workshops).

1. “An International Course on Surveying & Evaluating Ethical Review Practices” one day workshop for trainee surveyors on 23<sup>rd</sup> February 2009.
2. Training Workshop in ‘Ethical Aspects of Clinical Trials’ on 18<sup>th</sup> April 2009 (lay person)
3. Training Workshop “Good Clinical Practices“ on 11<sup>th</sup> Septembr 2009.

International recognition of the ECRHS will benefit the faculty members and students conducting research in the following ways in future.

- Ensuring optimum safety and wellbeing of patients participating in research
- Ensuring the highest ethical standard in review of research projects
- Assurance of adherence by the researchers to high scientific standard in conduct of research projects.
- Better research and funding opportunities from industry, the Government of India and foreign institutions.

3) **Appointment of a new Sub Committee** under the ECRHS for review of Serious Adverse Events (SAEs) – In keeping with recommendations of the SIDCER surveyors a new sub committee was formulated with Dr. Urmila Thatte as chairperson and Dr. Raakhi Tripathi (Co-opted member) as member secretary. The SOPs regarding formulation and activities of subcommittee were included in SOP 2.

- 4) **GCP Workshop for ECRHS and CARE members** - The ECRHS organized and conducted one day GCP Workshop for the ECRHS and CARE members of the Seth GS Medical College and KEM Hospital on "Ethics in Clinical Research" on 11<sup>th</sup> September 2009.
- 5) **Dr. Sandeep Bavdekar, one of the ECRHS member, published an article** entitled, "Informed consent documents submitted for initial review: what do they state about compensation for injured research participants?" in the Indian Journal of Medical Sciences based on the review of Informed Consent Documents submitted to the ECRHS in the last 2 years.

### Constitution of the ECRHS

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. Padmaja Marathe	Member Secretary	Associate Professor (Pharmacology & Therapeutics) GSMC & KEMH	M.D.	F
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. Sunil Kuyare	Member	Assistant Professor, (Microbiology) GSMC & KEMH	M.D., DHA, FME.	M
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 Hospital Mumbai Hindusabha	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

**Dr. Padmaja Marathe**  
**Member Secretary,**

**Dr. M. L. Kothari**  
**Chairperson,**