

1st FERC National Conference on Research Ethics

Organized by Tata Memorial Hospital in Association with KEM Hospital, Mumbai

5- 6 Nov 2011, Choksi Auditorium, TMH, Mumbai

08.30 a.m. – 9.30 a.m.	REGISTRATION (with Tea)		
9.30 a.m. – 10.00 a.m.	INAUGURATION		
	Welcome Address	Dr. R.A. Badwe	
	About FERC	Dr V M Muthuswamy	
	Introduction to Conference	DrU Thatte	
	Key note address	Dr. P.L. Tandon	
	Vote of thanks	Dr. Medha Joshi	
10.00 a.m. – 10.30 a.m.	Tea Break with snacks		
10.30 a.m. – 12.30 p.m.	Session I: Ethical Issues in Initial review: Special Situations		
Chairpersons : Dr. Gouri Devi , Dr. Vasantha Muthusawamy			
	Topic	Speakers	Affiliations
	Oncology Studies	Dr Reena Nair	Professor, Dept of Med. Oncology, TMH, Mumbai
	Non therapeutic studies	Dr Nithya Gogtay	Associate Professor, Dept of Clin Pharmacology, KEM Hospital Mumbai
	HIV	Dr Swarna Lakshmi	Manager- IRB, YRG Care, Chennai
	Vaccines and community	Dr Amar Jesani	Trustee, and Editor, IJME, Centre for Ethics and Rights, Mumbai
12. 30 p.m. - 1.30 p.m.	Session II : Panel Discussion: Compensation Issues for Research Related Injury		
Moderators - Dr. S D Seth, Dr. Nandini Kumar			
		Panelists	Affiliations
	Community representative	Ms. Manisha Naik Dalal	EC Member, KEM Hospital., Mumbai
	Industry	Dr Arun Bhatt and Surinder Kher	President.,ClinInvent, Mumbai / CEO Asia, Manipal Accunova Bangalore
	Lawyer	Justice Rangarajan	Former Judge, High Courts of Madras and Andhra Pradesh

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	Investigator	Dr Vyankatesh Shivne	Consultant Diabetologist, KEM Hospital, Mumbai
1.30 p.m. - 2.00 p.m.	Lunch		
2.00 p.m. - 4.00 p.m.	Session III: Challenges for Ethics Committees		
Chairpersons : Dr. SM Karandikar, Dr. V R Joshi			
Time	Topic	Speakers	Affiliations
	Invited Talks		
	Challenges for Ethics Committees: Experiences	Dr Kusum Verma	Senior Consultant, Dept.of Cytopathology Gangaram Hospital, Delhi
	Challenges for Ethics Committees: Experiences	Dr Manorama Thomas	Emeritus Professor St. Johns Med. College, Bengaluru
	Free Papers		
	Challenges faced by Members of Institutional Ethics Committees: a Focus on the Non-medical/non-technical Ethics Committee Member	Dr. R.Khandari	Dept. of Social Medicine and Community Health School of Social Sciences JNU, New Delhi
	Non-technical Members: their special Contributions to Human Ethics Committees and the Challenges they face	Dr. T. George	BARC, Mumbai
	The challenge of capacity building in Ethics committees: myth or reality?	Dr. V. S. Padbidri	KEM Hospital Research Centre, Pune
	Forming Joint Forum of Ethics Committees at Local Level	Dr. Rashmi Kadam	Quality Assurance Manager, Chest Research Foundation, Pune
	Reviewing public health and social science health research, the challenges of collaboration, capacity building and defining standards	Dr. Neha Madhiwalla	CEHAT (Centre for Enquiry Into Health and Allied Themes) Member Secretary, Multi-institutional Ethics Committee
	Establishment of an Intersystem Ethics Committee & Capacity Building of EC members	Dr. Jayashree Joshi	Inter System Biomedical Ethics Committee, Mumbai
4.00 p.m. - 4.30 p.m.	Tea Break		
4.30 p.m.- 5.30 p.m.	Session IV: Ongoing Review Process		
Chairpersons : Dr. Nargis Mahaluxmiwala, Dr. Madhuri Gore			
Time	Topic	Speakers	Affiliations
Curtain Raiser	Evaluation of SAE Reports: An Ethical Perspective	Dr. Raakhi Tripathi	Associate Professor, Dept. of Pharmacology and Therapeutics, KEM H

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	Safety Review	Dr. Sarbani Ghosh Laskar	Associate Professor, Dept of Radiation Oncology, TMH, Mumbai
	On Site Monitoring	Dr. Paul Kumaran	Assistant Director, TRC - Madurai Unit, Madurai
	Protocol Deviation	Dr. Viraj Rajadhyaksha	Associate Director, Sanofi -Aventis P Ltd Mumbai
	End of Day One		

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Day Two - 6th Nov 2011			
08.30AM-09.00AM	Tea & Breakfast		
09.00 a.m. -11.00 a.m.	Session V: Regulating Ethics Committees		
Chairpersons: Dr Christina Torres, Dr. V. Muthuswamy			
Time	Topic	Speakers	Affiliations
09.00 a.m. -11.00 a.m.	The Indian Experience	Dr Roli Mathur	Scientist 'C', Division of Basic Medical Sciences, ICMR, Delhi
	The FERCAP Experience	Dr Christina Torres	Co-Ordinator, FERCAP, WHO-TDR Clinical Coordination and Training Center , Thammasat University, Rangsit Campus Klongluang, Thailand
	The US Experience	Ms. Louise Winstanly	Adjunct Assistant Professor, UNC Gillings School of Global Public Health USA
	The AAHRPP Experience	Dr M A Speers	The Association for Accreditation of Human Research Participant Protection Programs, (AAHRPP), USA
	WHO Perspective	Dr. Madhur Gupta	WHO-India, New Delhi
Tea Break			
11.00 a.m. - 11.30 a.m.	Session VI: Free Paper (Compensation)		
11.30 a.m.- 1.00 p.m.	Session VI: Free Paper (Compensation)		
Chairpersons : Dr Roli Mathur, Dr. Madhur Gupta			
Time	Topic	Speakers	Affiliation
11.30 a.m. - 1.00 p.m.	Compensation for Participation in Research: A Review of Protocols and Informed Consent Documents Submitted for Review to two Ethics Committees	Dr. PA Marathe	Dept of Pharmacology, KEM Hospital Mumbai
	Compensation by insurance.	Dr. Sreenagamani Penupothu	Dept. of Pharmacology, Rangaraya Medical College,Kakinada-533001.
	Compensation to Clinical Trial Participants	Dr. Veena Joshi	Deenanath Mangeshkar Hospital and Research Centre, Erandavane, Pune 411004.
	Compensatory issues in clinical trials – an ethical review	Dr Dinesh K Dhodi	Assistant Professor, Dept. of Pharmacology, Sir J.J Hospital & Grant Medical College, Mumbai

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1.00 p.m. - 1.30 p.m.	Lunch		
1.30 p.m. - 3.30 p.m.	Session VII: Free Paper (Other)		
Chairpersons: Dr. Usha Rani, Dr. Shishir Gokhale			
1.30 p.m. - 3.30 p.m.	Invited Talk		
	Empowering the patient	Dr. Claire Anderson	Professor of Social Pharmacy, Faculty of Science, Nottingham University
	Free Papers		
	Unethical Problems of Dentistry in Bangladesh	Dr. Arup Kumar Saha	Lecturer Dental Public Health, City Dental College Bangladesh
	Ethics in research studies done by post graduate students towards their dissertation	Dr. Satyajit Pattnaik	Assist Prof, Community Medicine, Kalinga Inst. Of Med Scs., Bhubhaneshwar
	Towards a seamless review of multinational human subjects research: experience from the phfi-emory center of excellence partnership	Dr. Hemalatha Somsekhar	Academic Co-ordinator, Public Health Foundation of India, New Delhi, India
	Awareness about Ethics Committee amongst the medical teachers in a medical college	Dr. Vikram A Londhey	Medicine Department, TNMC and BYL Nair Ch Hospital, Mumbai 400008.
	Ancillary care – Who should hold the Bag?	Dr. Vasavi Gedela	2 nd year PG, Dept of Pharmacology, Rangaraya Medical College, Kakinda AP.
	Understanding why participants participate in clinical trials and their degree of comprehension of the informed consent process.	Dr. Renuka Munshi	Dept. of Clinical Pharmacology, TN Medical College & BYL Nair Ch Hospital, Mumbai Central, Mumbai 400 008
	Documentation of Ethics practices in 4 major Indian Journals	Dr. M Belhekar	Dept. of Clinical Pharmacology, TN Medical College & BYL Nair Ch Hospital, Mumbai Central, Mumbai 400 008
	Informed Consent in Biomedical Research: Sounds simple but difficult to comprehend'	Dr. A.M. Khan and J. Mahanta	Regional Medical Research Centre, ICMR, Dibrugarh – (Assam) India
	Informed Consent Form and “BLOOPERS”	Dr. Naresh M Singh	Advocate Member, Independent Ethics Committee , Primarily associated with KEM Hospital Research Centre Pune
	Completeness of Project Application Forms Submitted To Institutional Ethics Committees (IEC) of A Tertiary Care Hospital	Dr. YC Shetty	Dept. of Pharmacology & Therapeutics, Seth GS Medical College & KEM Hospital, Mumbai .
	Knowledge, awareness and attitude towards bioethics & clinical research among medical interns in Tamil Nadu, South India	Dr. Harivenkatesh N.	Final Yr MD-Pharmacology Resident, Sri Ramachandra Medical Chennai
3.30 p.m. - 4.30 p.m.	Session VII: Empowering the Patient		
Chairpersons: Ms. Louise Winstanly, Dr. Paul Kumaran			
3.30 p.m. - 4.30 p.m.	Empowering patients - MSSI Indian scenario	Ms Sheela Chitnis	Chairperson, Multiple Sclerosis Society of India, Mumbai Chapter

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	Clinical Trials Registry of India	Dr. Abha Agarwal	CTRI, New Delhi
	ICD Video / speaking books	Dr. Mohanish Anand	Sr. Director & Regional Head Clinical Operations Asia , Pfizer India Ltd.
4.30 p.m. - 5.00 p.m.	Valedictory Session		
	Introduction	Dr V Muthuswamy	President, FERCI
	Conference Report	Dr Y Shetty / Dr R Tripathi	Conference Rapporteurs
	Valedictory Address	Dr. Manu Kothari	Chairperson, EC , KEM hospital Mumbai
	Vote of thanks	Dr U. Thatte	Secretary, FERCI
End of Conference			