RIS
Research and Information System for Developing Countries

Workshop on Clinical Trial Regulations of India

At 10:00 am to 05:00 pm
On Wednesday, 2 December, 2015
At G. Parthasarathi Conference Hall RIS, India Habitat Centre, New Delhi

Time	Session	Speakers/Panellists
09:30 – 10:00	Registration	
10:00 – 11:00	**Inaugural Session**	
	Welcome Remarks	**Prof. T C James**, Visiting Fellow, RIS
	Remarks	**Prof. Sachin Chaturvedi** , DG,RIS **Dr Manisha Shridhar**, Regional Advisor, IPRs and Trade and Health, HSD, SEARO, WHO **Dr G N Singh**, DCGI* **Dr Nandini K. Kumar**, Former Deputy Director General Sr. Grade (ICMR).
	Presentation of the Study	**Mr Zakir Thomas**, Team Leader, Clinical Trial Study, RIS
	Inaugural Address	**Prof. S.K. Brahmachari, FNA** Academy Professor and Former Director General, CSIR and Secretary, DSIR Academy of Scientific and Innovative Research*
11:00 – 12:30	**Technical Session I**	**Theme: Regulatory Approval Process** **Issues:** • Quality of the approval process • Views on three-tier system • Comparison with Global Best Practices
	Panel	**Dr K Satyanarayana**, Former DDG, ICMR, New Delhi **Dr Suneela Garg**, Director Professor, Deptt of Community Medicine, Maulana Azad Medical College **Ms Leena Meghaney**, Regional Head - South Asia, MSF – Access Campaign **Dr Y K Gupta** *Professor and Head, Department of Pharmacology, AIIMS, New Delhi** **Dr Colin Gonsalves**, Founder, Human Rights Law Network (HRLN)* **Dr Sarala Balachandran**, Chief Scientist, CSIR &

		Project Director, Open Source Drug Discovery (OSDD)Unit and Professor, The Academy of Scientific & Innovative Research (AcSIR), CSIR
12:30 – 01:30	Lunch	
01:30-02:30	**Technical Session II**	**Theme: Working of Ethics Committee** **Issues:** • Comparison with Global Best Practices • Working of Ethics Committees vis *a vis* their objectives • Issue of conflict of Interest • Expertise of Ethics Committee Members
	Panel	**Dr Nandini K. Kumar,** Former DDG (SG), ICMR **Dr Anant Bhan**, Researcher, Global Action for Health, Mumbai **Dr Swati Subhodh**, Member, Ethics Committee, NITRD, Delhi **Dr Mira Shiva**, Former Chairperson HAI-AP , Founder Member PHM and Member Advisory Council , Course Coordinator Initiative for Health & Equity in Society. **Dr S Visalakshi**, Sr Research Consultant, CENTAD, New Delhi* **Dr Jayanti**, Apollo Hospitals*
02:30-03:30	**Technical Session III**	**Theme: Prior Informed Consent** **Issues:** • Comparison with Global Best Practices • Socio-cultural issues in getting audio-visual PIC • Impact of the asymmetric relationship between doctor and patient on PIC
	Panel	**Dr Shaheed Jawahar**, NIRT Chennai **Dr V P Myneedu**,HOD, Department of Microbiology, NITRD **Dr Anant Bhan,** Global Action for Health **Dr. Shinjini Bhatnagar**, Dean (Clinical Research), Head-PBC, Coordinator-CBD, Translational Health Science and Technology Institute* **Ms Kajal Bhardwaj**, Independent Lawyer, New Delhi* **Ms Leena Meghaney**, MSF
03:30- 04:30	**Technical Session IV**	**Theme:** Compensation Guidelines **Issues:** • Comparison with Global Best Practices • Liability Issues • Role of institutions • Delivery of timely compensation • Role of Insurance
	Panel	**Dr Y Madhavi**, Sr Principal Scientist

		NISTADS **Sh Anand Grover**, Sr. Advocate, Lawyer's Collective **Dr Roli Mathur**, Basic Sciences Division, ICMR **Dr Reji K Joseph**, Associate Professor, ISID
04:30-05:00	**Concluding Session**	
	Presentation of Conclusions	**Prof T C James, Mr Zakir Thomas, Ms Nivedita Saksena**