

Indian Society for Clinical Research
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International Clinical Trials Day, May 20 2017 (ISCR, KEM Hospital, Tata Hospital, NIRRH)



Venue: Clinical Pharmacology seminar room, KEM Hospital, Mumbai

Date: 20-May-2017, **Timing:** 2.30 to 5:00 pm

Agenda:

Time	Topics	Speakers
2.30 – 2.45 pm	Introduction and brief about ICTD	EC Chair and / or KEM hospital Chair/ designee
2.45 – 2.50 pm	Educational film on Clinical Trial	Organizer
2.50 – 3.30 pm	Role of ECs ensuring Patient Safety in Clinical Trials Panel Discussion Moderator:	Dr. Urmila Thatte, KEM Hospital Dr. Yasashri Shetty, KEM Hospital
	Safeguard the rights, safety and well-being of all trial participants	
	Informed Consent and recruitment methods used in trial	
	Risk benefit analysis while reviewing study protocol	
	Reviewing safety reports and ECs role in review of Data Safety Monitoring Board	
	Compensation for study related injury	
	Continuing review of each ongoing trial at intervals appropriate to the degree of risk to subjects	
	Confidentiality and privacy of subject is protected	

	Compliant and concerns of subjects are addressed and managed	
	EC legal action / Penal provision	
	Question/Answer	
3.30 – 4.10 pm	Ethics Committee Accreditation Panel Discussion Moderator:	Dr. Urmila Thatte, KEM Hospital Dr. Yasashri Shetty, KEM Hospital
	Importance of EC accreditation – Need of an era - Benefits to Subjects, Sites, Investigators, Regulatory Bodies, Sponsors	
	ECs functioning according to SOPs and local regulatory requirements	
	Mandatory trainings of EC members	
	Documentation practice streamlined including archival process	
	Empowered ECs to conduct ethical review and ensure human research protection	
	Improved quality	
	Communication established between stakeholders	
	Question/Answer	
4.10-4.30	Interactive Q/A & Concluding remark	All participants
4.30-5.00	Tea Break	

Panelist for Role of ECs ensuring Patient Safety in Clinical Trials

1. Dr. Chetan Desai
2. Dr. Medha Joshi
3. Suneela Thatte
4. Dr. Lalita Savardekar
5. Veena Johari
6. Manishal Dalal

Panelist for Ethics Committee Accreditation

1. Dr. Arun Bhatt
2. Dr. Sanish Davis
3. Dr. George Karimundacka
4. Sharmilla Jalgaonkar
5. Dr. Girish Chinnaswamy