

# Current Ethical and Regulatory Requirements for Clinical Trials or Research

ESIC Medical College, Faridabad

August 08 - 09, 2017

## Program Agenda

August 08, 2017

Time	Title (Learning Objectives)	Presenter
09:00 – 09:30	Registration	<b>Ms. Neha Mishra</b> , Training Coordinator, CDSA
09:30 – 10:00	<ul style="list-style-type: none"> <li>Welcome Address</li> <li>Keynote Address</li> <li>Course Introduction &amp; Overview</li> <li>Vote of Thanks</li> </ul>	<ul style="list-style-type: none"> <li><b>Dr. Asim Das</b> Dean, ESIC Medical College, Faridabad</li> <li><b>Dr. Shinjini Bhatnagar</b> Dean, Clinical Research, THSTI</li> <li><b>Dr. Sucheta Banerjee Kurundkar</b> Director Training, CDSA</li> <li><b>Dr. Anil Kumar Pandey</b> Member Secretary, Institutional Ethics Committee, ESIC Medical College, Faridabad</li> </ul>
10:00 – 10:30	<b>Group Photograph &amp; Networking Tea</b>	
10:30–11:30	Regulation and Guidelines for Ethics Committee in India	<b>Dr. V. G. Somani</b> JDC(I), CDSCO HQ, New Delhi
11:30 –12:30	Ethics Committee: <ul style="list-style-type: none"> <li>Composition</li> <li>Roles and Responsibilities of Members</li> </ul>	<b>Dr. Vasantha Muthuswamy</b> Former Senior Deputy Director General, ICMR; Advisor, IHEC, PSGIMSR, Coimbatore
12:30 –13:15	<b>Lunch Break</b>	
13:15–14:45	Ethics Committee: <ul style="list-style-type: none"> <li>Standard Operating Procedures</li> <li>Functioning</li> </ul>	<b>Dr. Nandini K. Kumar</b> Former Deputy Director General (Sr. Grade), ICMR, Dr. TMA Pai Endowment Chair, Manipal University; Adjunct Faculty, CDSA
14:45 –15:45	Ethics Committee: <ul style="list-style-type: none"> <li>Review and Approval Process</li> </ul>	<b>Dr. Vasantha Muthuswamy</b> Former Senior Deputy Director General, ICMR; Advisor, IHEC, PSGIMSR, Coimbatore
15:45 –16:00	<b>Tea/Coffee Break</b>	
16:00 –17:30	Exercises, Case studies, Group activities	<b>Dr. Nandini K. Kumar</b> Former Deputy Director General (Sr. Grade), ICMR, Dr. TMA Pai Endowment Chair, Manipal University; Adjunct Faculty, CDSA
>17:30	Open Forum for Q & A	

**August 09, 2017**

Time	Title (Learning Objectives)	Presenter
09:00 – 09:30	Recap	Participants
09:30 – 10:15	<ul style="list-style-type: none"> <li>Submission of Dossier to Ethics Committee</li> <li>Monitoring</li> </ul>	<b>Dr. Urmila Thatte</b> Professor & Head of Clinical Pharmacology, Seth G S Medical College & KEM Hospital, Mumbai
10:15 – 10:30	<b>Tea/Coffee Break</b>	
10:30 – 11:15	Record Keeping: Do's & Don't	<b>Dr. Nandini K. Kumar</b> Former Deputy Director General (Sr. Grade), ICMR, Dr. TMA Pai Endowment Chair, Manipal University; Adjunct Faculty, CDSA
11:15–12:00	Investigator's responsibilities	<b>Dr. Urmila Thatte</b> Professor & Head of Clinical Pharmacology, Seth G S Medical College & KEM Hospital, Mumbai
12:00–12:45	Process of CDSCO Registration for Ethics Committee	<b>Shri. A. B. Ramteke</b> Former Joint Drugs Controller (India), CDSCO, HQ, New Delhi & Consultant Regulatory Affairs, CDSA
12:45 –13:30	<b>Lunch Break</b>	
13:30 – 14:15	NABH Accreditation	<b>Dr. Sucheta Banerjee Kurundkar</b> Director Training, CDSA
14:15 – 15:15	Exercises, Case studies, Group activities	<b>Dr. Nandini K. Kumar</b> Former Deputy Director General (Sr. Grade), ICMR, Dr. TMA Pai Endowment Chair, Manipal University; Adjunct Faculty, CDSA
15:15 – 15:30	<b>Tea/Coffee Break</b>	
15:30 – 16:30	Exit Assessment	
16:30 – 17:30	Open Forum for Q & A and Feedback Distribution of Certificates	

**Happy Learning!!**