# Current Ethical & Regulatory Requirements for Clinical Trials / Research

## ESIC Medical College, Faridabad

## August 08 - 09, 2017


### OBJECTIVE

To strengthen and empower the Institutional Ethics Committee (IEC) members to ensure that they understand scientific, regulatory norms, ethical design, conduct and reporting of clinical research that will be of uniform nature and meets national and international quality standards.

### EXPECTED OUTCOME

At the end of the program, the participants will be aware about the current guidelines and regulations for the conduct of clinical trials or research in India so that they can ensure that the right, safety and well-being of human participants involved in research are well protected.

### TARGET PARTICIPANTS

Members from Ethics Committees will be given priority. Investigators and clinical trial or research team members are encouraged to apply.

**10 CME Credit hours**

### REGISTRATION:

Application will be considered on a first come first serve basis.

| Registration Fees (For External Candidates) | |
|---|---|
| **Fee** | Rs. 2000 |
| **GST @ 18%** | Rs. 360/- |
| **Total** | Rs. 2,360/- |

Please apply in the prescribed application format available on the website:

**Link for Registration**

http://cdsaindia.in/node/226

**Limited Seats 50**

**Contact Information**

**Ms. Neha Mishra/ Dr. Sucheta B. Kurundkar**

**Training Department,**

**Clinical Development Services Agency (CDSA), Faridabad**

**Email :** training.cdsa@thsti.res.in

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## ESIC Medical College & Hospital, Faridabad

**August 08 - 09, 2017**

### Program Agenda

**August 08, 2017**

| Time | Title (Learning Objectives) | Presenter |
|---|---|---|
| 09:00 – 09:30 | Registration | **Ms. Neha Mishra**, Training Coordinator, CDSA |
| 09:30 – 10:00 | • Welcome Address<br>• Keynote Address<br>• Course Introduction & Overview<br>• Vote of Thanks | • **Dr. Asim Das** Dean, ESIC Medical College & Hospital, Faridabad<br>• **Dr. Shinjini Bhatnagar** Dean, Clinical Research, THSTI & Incharge, CDSA<br>• **Dr. Sucheta Banerjee Kurundkar** Director Training, CDSA<br>• **Dr. Anil Kumar Pandey** Member Secretary, IEC, ESIC Medical College & Hospital, Faridabad |
| 10:00 – 10:30 | **Group Photograph & Networking Tea** | |
| 10:30 – 11:30 | Ethics Committee:<br>• Composition<br>• Roles & Responsibilities of members | **Dr. Vasantha Muthuswamy** Former Senior Deputy DG, ICMR; President, FERCI |
| 11:30 – 12:30 | Ethics Committee:<br>• Standard Operating Procedures<br>• Functioning | **Dr. Nandini K. Kumar** Former Deputy DG (Sr. Grade), ICMR; Adjunct Faculty, CDSA |
| 12:30 – 13:15 | **Lunch Break** | |
| 13:15 – 14:45 | Ethics Committee:<br>Review and Approval Process | **Dr. Vasantha Muthuswamy** Former Senior Deputy DG, ICMR; President, FERCI |
| 14:45 – 15:45 | Regulation and Guidelines for Ethics Committees in India | **Dr. V. G. Somani** Joint Drugs Controller (India), CDSCO, DGHS, MoHFW, New Delhi |
| 15:45 – 16:00 | **Tea/Coffee Break** | |
| 16:00 – 17:30 | Exercises: Case studies, Group activities | • **Dr. Vasantha Muthuswamy** Former Senior Deputy DG, ICMR; President, FERCI<br>• **Dr. Nandini K. Kumar** Former Deputy DG (Sr. Grade), ICMR; 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 | • Submission of dossier to Ethics Committee<br>• Monitoring | **Dr. Renu Saxena**<br>Professor & Head of Haematology, AIIMS, New Delhi |
| 10:15 – 10:30 | **Tea/Coffee Break** | |
| 10:30 – 11:15 | Record Keeping and Archiving | **Dr. Nandini K. Kumar**<br>Former Deputy DG (Sr. Grade), ICMR; Adjunct Faculty, CDSA |
| 11:15 – 12:00 | Investigator's Responsibilities | **Dr. Vasantha Muthuswamy**<br>Former Senior Deputy DG, ICMR; President, FERCI |
| 12:00 – 12:45 | CDSCO registration process for Ethics Committees | **Shri. A. B. Ramteke**<br>Former Joint Drugs Controller (India), CDSCO, HQ, New Delhi & Consultant Regulatory Affairs, CDSA |
| 12:45 – 13:30 | **Lunch Break** | |
| 13:30 – 14:15 | NABH Accreditation | **Dr. B. K. Rana**<br>Former Director, NABH |
| 14:15 – 15:15 | Exercises, Case studies, Group activities | • **Dr. Vasantha Muthuswamy**<br>Former Senior Deputy DG, ICMR; President, FERCI<br>• **Dr. Nandini K. Kumar**<br>Former Deputy DG (Sr. Grade), ICMR; Adjunct Faculty, CDSA |
| 15:15 – 15:30 | **Tea/Coffee Break** | |
| 15:30 – 16:30 | Exit Assessment | **Dr. Sucheta Banerjee Kurundkar**<br>Director Training, CDSA |
| 16:30 – 17:30 | Open Forum for Q & A and Feedback<br>Distribution of Certificates | |

**Happy Learning!!**