

GCP Workshop for Researchers

Organized by the Forum for
Ethics Review Committees in Sri Lanka



Day 1: 16th March 2020

Time	Topic	Speaker
8.00 am – 8.45 am	Registration	
8.45 am – 9.00 am	Introduction	President FERCSL
9.00 am - 9.30 am	Research ethics in Clinical Trials	Prof.Chandanie Wanigatunge Chairperson, FERCSL Chairperson, ERC SLMA
9.30 am - 10.00 am	Drug development process	Prof. Channa Ranasinha Professor in Pharmacology, FM, Kelaniya
10.00 am - 10.45 am	Introduction to GCP, Principles, What is GCP? Need for GCP?	Prof. Priyadarshani Galappaththy Professor in Pharmacology FM, Colombo
10.45 am – 11.00 am		Tea
11.00 am – 11.45 am	Role and Responsibilities of PI	Prof. Priyadarshani Galappaththy Professor in Pharmacology FM, Colombo
11.45 am – 12.15 pm	Clinical Trial protocol and Investigation Brochure	Prof.G R Constantine Professor in Clinical Medicine, FM, Colombo
12.15 pm – 1.00 pm	Participant safety and adverse effects	Prof. Shalini Sri Ranganathan Professor in Pharmacology FM, Colombo
1.00 pm – 1.45 pm	Documentation and record keeping	Dr. Noel Somasundaram Consultant Endocrinologist
1.45 pm		Lunch

Day 2 – 17th March 2020

Time	Topic	Speaker
9.00 am – 9.45 am	Ethics review committee – function with special ref to GCP and Clinical Trials	Dr. Panduka Karunanayake Senior Lecturer in Clinical Medicine, FM, Colombo Secretary ERC, FM Colombo
9.45 am – 10.30 am	Informed consent	Dr. Manouri Gamage Senior Lecturer, FMS, USJ
10.30 am to 11.00 am	Regulatory requirements for clinical trials and legal framework	Mr. Arjuna Pathmaperuma Regulatory Pharmacist NMDRA/ SCOCT
11.00 am – 11.15 am	Tea	
11.15 am – 11.45 am	Investigational products	Prof. Shalini Sri Ranganathan Professor in Pharmacology FM, Colombo
11.45 am – 12.15pm	Role of the sponsor & Contract Research Organization (CRO)	Prof. H Asita de Silva Senior Professor of Pharmacology Chairman of the National Medicines Regulatory Authority
12.15 pm – 12.45 pm	Research Misconduct and Conflict of Interest	Dr. Enoka Corea ERC, Colombo