



GCP Workshop for Researcher

Organized by the Forum for
Ethics Review Committees in Sri Lanka

Moderator: Dr. Malik Fernando



Day 1: 28th June 2021

Time	Topic	Speaker
9.00 am	Introduction	President SLMA 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 - 10.30 am	Introduction to GCP, Principles, What is GCP? Need for GCP?	Prof. Chandanie Wanigatunge Chairperson, FERCSL Chairperson, ERC SLMA
10.30 am – 11.00 am	Role and Responsibilities of PI	Dr. Lalith S. Wijyaratne, Consultant Rheumatologist
11.00 am – 11.30 am	Break	
11.30 am – 12.00 pm	Clinical Trial protocol and Investigation Brochure	Prof. G R Constantine Professor in Clinical Medicine, FM, Colombo
12.00 pm – 12.30 pm	Participant safety and adverse effects	Prof. Shalini Sri Ranganathan Professor in Pharmacology FM, Colombo
12.30 pm – 1.00 pm	Documentation and record keeping	Dr. Noel Somasundaram Consultant Endocrinologist
	End of Day one	

Day 2 : 5th July 2021

Time	Topic	Speaker
9.00 am – 9.30 am	Ethics review committee – function with special ref to GCP and Clinical Trials	Prof. Panduka Karunanayake Professor in Clinical Medicine, FM, Colombo
9.30 am – 10.00 am	Informed consent	Dr. Manouri Gamage Senior Lecturer, FMS, USJ
10.00 am to 10.30 am	Regulatory requirements for clinical trials and legal frame work	Mr. Arjuna Pathmaperuma Regulatory Pharmacist Clinical Trials Evaluation Committee /NMRA
10.30 am – 11.00am	Tea	
11.00 am – 11.30 am	Investigational products	Prof. Shalini Sri Ranganathan Professor in Pharmacology FM, Colombo
11.30 am – 12.00 pm	Role of the sponsor & Contract Research Organization (CRO)	Prof. H Asita de Silva Senior Professor of Pharmacology Professor in Pharmacology, FM, Kelaniya
12.00 pm – 12.30 pm	Research Misconduct and Conflict of Interest	Prof. Enoka Corea Professor in Microbiology, FM, Colombo