



GCP Workshop for Researchers

Organized by the
Forum for Ethics Review Committees in Sri Lanka



Date: 10th August 2023

Venue – SLMA Auditorium

Time	Topic	Speaker
8.45 am	Introduction	President SLMA/President FERCSL
9.00 am - 9.30 am	What is GCP? - Introduction, Principles and Needs and Drug development process	Prof. Chandanie Wanigatunge Chairperson, FERCSL Chairperson, ERC SLMA
9.30 am - 10.15 am	CT protocol and investigational products	Prof. Shalini Sri Ranganathan Professor in Pharmacology Faculty of Medicine, University of Colombo
10.15 am - 10.45 am	Role and Responsibilities of PI including documentation and record keeping	Professor Priyadarshani Galappaththy Professor of Pharmacology, Faculty of Medicine, University of Colombo
10.45 am – 11.15 am	Participant safety and adverse effects	Prof. Shalini Sri Ranganathan Professor in Pharmacology Faculty of Medicine, University of Colombo
11.15 am – 11.30 am	Break	
11.30 am – 12.00 pm	Ethics Review Committee Functions (special reference to GCP and Clinical Trials)	Prof. Panduka Karunanayake Professor in Clinical Medicine, Faculty of Medicine, University of Colombo
12.00 pm - 12.30 pm	Regulatory requirements for clinical trials and legal frame work	Mr. Arjuna Pathmaperuma Pharmacist, Surgical Non-Consumable National Eye Hospital, Colombo
12.30 pm - 1.00 pm	Responsibilities of the stake holders to facilitate interventional research	Prof. H Asita de Silva Senior Professor of Pharmacology Professor of Pharmacology, Faculty of Medicine, University of Kelaniya
1.00 pm – 1.30 pm	Informed consent	Prof. Naazima Kamardeen Professor of Commercial Law, University of Colombo