MEENAKSHI
ACADEMY OF HIGHER EDUCATION & RESEARCH
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MEENAKSHI MEDICAL COLLEGE HOSPITAL AND RESEARCH INSTITUTE

Training Program on Good Clinical Practice
Date: 30th July 2025
Program Schedule

S.No	Time	Topic	Objectives	Resource faculty
1	08.30 - 09.00 am	**Registration & Pre Test**		
2	9:00 - 9:15 am	**Inaugural Session**		
3	09.15 - 10.30 am	Introduction to Good Clinical Practice (GCP)	Define GCP and its importance in clinical research. Discuss the ethical and scientific principles underlying GCP. Introduce key regulatory requirements for clinical trials (NDCT rules 2019)	**Dr.Parimala K** Professor & HOD, Department of Pharmacology MMCH&RI
4	10:30 – 11:15 am	Ethical Principles in Clinical Research	Explore core ethical principles: autonomy, beneficence, non-maleficence, and justice Discuss the role of Institutional Ethics Committee (IECs).	**Dr. V.P Karthik** Associate Professor, Department of Pharmacology, Sri Ramachandra Medical College&Research Institute, Chennai
5	11:15 – 11:30 am	**Break**		

6	11.30am - 12.15pm	Clinical Trial Design, Protocol development for CT and Conduct of RCT	Discuss different types of clinical trials (e.g., randomized controlled trials etc) Explain key aspects of clinical trial design, including protocols, randomization, and blinding.	**Dr. V.P Karthik** Associate Professor, Department of Pharmacology, Sri Ramachandra Medical College&Research Institute, Chennai
7	12:15 –1.00 pm	Roles and Responsibilities in Clinical Trials	Explore the roles and responsibilities of clinical investigators and research staff and sponsors	**Dr. Rajesh.R,** Professor, Department of Dermatology, MMCH&RI
8	1:00 –1.45 pm	**Lunch Break**		
9	1:45 - 2:30 pm	Informed Consent Process.	Details of the ICD (PIS & ICF) and importance of consent process.	**Dr. K. Shankar,** Professor, HOD, Department of Community Medicine, MMCH&RI
10	2:30 - 3:00 pm	Documents and Documentations in Good Clinical Practice	The documentation process and Archival in Clinical Trials. Identifying, reporting, and managing adverse events and serious adverse events.	**Dr.Pachamuthu Balakrishnan,** Professor & Chief Scientist – Infectious Diseases, Advanced Research Centre for Health Sciences, MAHER
11	3:00 - 3:15 pm	**Break**		
12	3:15 - 4:00 pm	Role of regulatory bodies and Consequences of GCP Non-compliance		**Dr. Punitha VC,** Research Coordinator, MMCH&RI
13	4:00 pm - 4:15 pm	**Valedictory and Certificate Distribution**		