

## **MEENAKSHI**

**ACADEMY OF HIGHER EDUCATION & RESEARCH** 

(DEEMED TO BE UNIVERSITY U/S 3 OF UGC ACT 1956)

MEENAKSHI MEDICAL COLLEGE HOSPITAL AND RESEARCH INSTITUTE

## [MEDICAL EDUCATION UNIT, MMCHRI]

Solicits your presence on the occasion of

## TRAINING PROGRAM ON GOOD CLINICAL PRACTICE

Date: 06th March 2025 || Time: 08.30 am to 04.30 pm

Venue: Skill Lab, Library Block, 2nd floor, MMCHRI

With the blessings of our Founder Chancellor Late Thiru. A. N. Radhakrishnan, M.A., D.Com.,

In the presence of

Mrs.Gomathi Radhakrishnan

Chief Patron

Mrs. Jayanthi Radhakrishnan, MBA

Chancellor

Mr. Akash Prabhakar, B.S. (Engg), MBA

Pro-Chancellor

Prof. Dr.C.Sridhar, MD,FIMSA

Vice-Chancellor

Prof. Dr.C.Krithika, MDS,Ph.D

**Pro-Vice Chancellor** 

Prof. Dr.V.Sureka Varalakshmi, M.Sc,Ph.D

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Dean

Prof. Dr.V.Eswari, MD

Vice Principal (Academics)

Prof. Dr.R.Muthulakshmi, MD

Vice Principal (Students Welfare)

**Organising Secretary** 

Dr.Punita.P,
MEU Coordinator, MMCHRI

**Organising Chairman** 

Dr.K.V.Rajasekhar Dean, MMCHRI

## PROGRAM SCHEDULE

S.No	Time	Торіс	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)	<b>Dr.Parimala K</b> 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	<b>Dr. Rajesh.R,</b> 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		<b>Dr. Punitha VC,</b> Research Coordinator, MMCH&RI
13	4:00 pm - 4:15 pm	Valedictory and Certificate Distribution		

The Postgraduate students are requested to pay Rs.250 for TNMC credit hours