SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH

SRI DEVARAJ URS MEDICAL COLLEGE

Tamaka, Kolar

OFFICE OF THE PRINCIPAL

Course in Ethics including Good Clinical Practices & Good Laboratory Practices on 19th & 20th November 2024 at Dr.B C Roy Hall (Library 1st floor).

SCHEDULE FOR COURSE ON ETHICS			
Time	**Topics**	**Objectives of the session**	**Resource Person**
9.00 am to 9.10 am	Pre-test & Ice breaking		Dr.Ashwini K Shetty Professor of Physiology SDUMC, Kolar
9.10 am to 10.15 am	Principles of Bioethics	• List the Principles of bioethics • Discuss the principles of bioethics in clinical practice	Dr.Kalyani R Professor of Pathology Director, Research and Development Cell, SDUMC SDUAHER, Kolar
10.30 am to 12.00 pm	Case Discussion on Principles of Bioethics Doctor patient relationships	• Discuss regarding the Principles of bioethics and application in clinical practice • Enumerate and describe professional qualities and roles of a physician and its application in clinical practice	Dr.Ashwini K Shetty Professor of Physiology SDUMC, Kolar & Dr.Geetha S Professor of Physiology SDUMC, Kolar
12.00 pm to 1.00 pm	Research ethics	• EC Functioning • Informed consent process • Confidentiality and Privacy • Publication ethics	Dr.Srinivasa Reddy P Professor of Forensic Medicine SDUMC, Kolar
1.00 pm to 1.15 pm	Post Test & Feedback		Dr.Rashmi G Professor of Ophthalmology SDUMC, Kolar
1.15 pm to 2.00 pm	Lunch		
2.00 pm to 2.45 pm	Good clinical Practices		Dr.Sarala N Director of Academic, SDUAHER Professor & HoD of Pharmacology SDUMC, Kolar
2.45 pm to 3.30 pm	Good Laboratory Practices		Dr.Arvind Natarajan Dean, AHS, SDUAHER Professor of Microbiology, SDUMC
3.30 pm to 3.45 pm	Post Test & Feedback		Dr.Rashmi G Professor of Ophthalmology SDUMC, Kolar

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH

(A DEEMED TO BE UNIVERSITY)

TAMAKA, KOLAR, 563103

On occasion of

SRI R L JALAPPA CENTENARY YEAR CELEBRATION

(1925-2025)

and

International Clinical Trial Day

20-05-2025

Clinical Trial Centre

(Division of Research & Development Cell)

In Association with

Department of Pharmacology

and

ISCR ACCRI and South Chapter

Organizing

CME

Good Clinical Practice (GCP)

on

Tuesday 20th May 2025

Time: 8:45 AM to 1:30 PM

Dr BC Roy Seminar Hall

1st floor, ULLRC

SDUAHER

In fond remembrance of Late Sri. R. L. JALAPPA
Founder Chairman, SDUET

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Medical Superintendent, RLJH & RC

Dr Arvind Natarajan
Dean, Faculty of AHBS, SDUAHER

Dr G Vijayalakshmi
Principal, SDUCON, SDUAHER

Dr Ashok Kumar BS
Principal, RL J College of Pharmacy, SDUAHER

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Organizing Chairpersons

Dr Kalyani R
Director
Research & Development Cell
SDUAHER

Dr Bhuvana K
Chief Co-ordinating Officer
Clinical Trial Centre
SDUAHER

Organizing Secretaries

Dr Sathishbabu P
Deputy Co-ordinator-1, CTC, SDUAHER

Dr Bhargavi S
Deputy Co-ordinator-2, CTC, SDUAHER

Organizing Committee Members

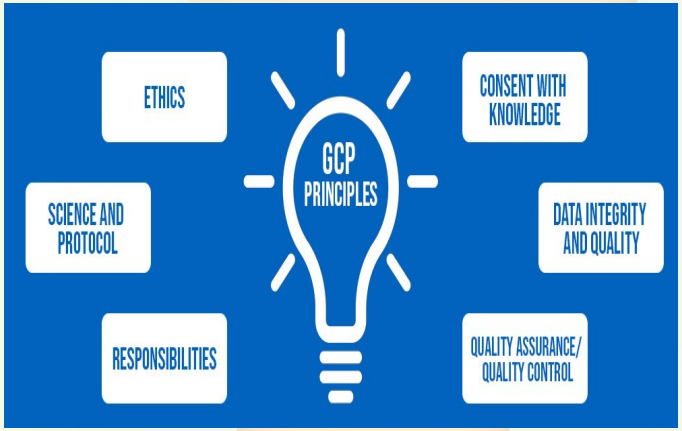
Dr Venkateswarlu Raavi
Deputy Co-ordinator, R & D, SDUAHER

Dr Lavanya Subhashini
Member, CTC, SDUAHER

Ms Mrudhula, Mr Madhuresh, Mrs Sumathi K, Mr Umashankar, CTC Team

Dear Participants,

The Clinical Trial Centre, RL Jalappa Hospital and Research Centre is pleased to extend a warm invitation to CME on Good Clinical Practice.



Good Clinical Practice (GCP) are guidelines and standards for conducting clinical trials involving human subjects, established by the International Council for Harmonization (ICH) of Technical Requirements for Pharmaceuticals for Human Use, specifically under the ICH E6 (R2) guidelines. Adherence to GCP ensures that clinical trials are conducted ethically, safely, and scientifically, facilitating development of new medical treatments and ensuring public trust in the research process.

Objectives

At the end of the program the participants should be able to

1. Explain the GCP, ICMR and NDCT 2019 guidelines for the conduct of clinical trials
2. Explain the process of documentation involved during the conduct of clinical trial
3. Explain the roles and responsibilities of sponsor and investigators in clinical trial

Programme schedule

TIMINGS	TOPICS	SPEAKER
8.45 –9:00 AM	Registration	
9.00 AM – 9.30 AM	About ISCR and ICTD, overview of clinical trials and why trials are needed in India	Dr Ananya Chakraborty Chair of ISCR ACCRI and Team
9:30 AM – 9:40 AM	GCP Guidelines - An overview	Dr Bhuvana K Prof of Pharmacology SDUMC, Kolar
9:40 AM – 10:10 AM	Inauguration and Tea Break	
10:10 AM – 10:45 AM	ICMR National Ethical Guidelines for Biomedical and Health Research involving human participants 2017 – An overview	Dr Sunil Kumar D Professor and Head, Community Medicine JSS Medical College, JSSAHER, Mysuru
10:45 AM – 11:30 AM	Clinal Trial Protocol, Essential Documents, New Drugs and Clinical Trials Rules, 2019	Dr Niveditha Director, Professor, Pharmacology ESIC Medical College & PGIMSR, Bangalore
11:30 AM– 12:10 PM	Ethics Committee: Guidelines, Constitution, roles & responsibilities and Informed consent Process	Dr. Praveen Kumar BA Professor of Community Medicine, PES Institute of Medical Science and Research, Kuppam, Andhra Pradesh
12.10 PM– 12.50 PM	Adverse events Documentation in Clinical Safety	Mr. Madhusudhan B Acharya, Associate Director, Drug Safety, Adjudication, Fortrea, Bangalore, Member, ISCR South Chapter
12:50 PM – 01:20 PM	Panel Discussion: Investigators: Roles and Responsibilities Chairperson : Dr Gopinath KS, Director, RLJIO, Surgical Oncologist, SDUMC Panelists: Dr Vengamma B, Neurologist, SDUMC Dr. Lokanatha D and Dr Sampath Kumar MN Medical Oncologists, SDUMC Moderator: Dr. Ravi M, Professor of Anaesthesiology, SDUMC	
1:20 –1:30 PM	Vote of Thanks and Valedictory	

Please click on the following link to register:

https://rb.gy/r8ipac

Mandatory Registration for the event (Free)
Session - Offline mode only

Certificate will be issued only on successful submission of the feedback form
Link for the feedback form will be shared to registered mail

For more details contact

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