

# One Week Online Training Course on BIOETHICS & GOOD CLINICAL PRACTICES (GCP)

# (22 -28 August, 2025)

# **Organized By**

Department of Health Research-Multidisciplinary Research Unit

Uttar Pradesh University of Medical Sciences, Saifai, Etawah, UP

(As per UP Government Act No 15 of 2016 to provide for establishment of a Medical Sciences University)

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Resilient Foundation For Academic Innovation & Scientific Research, New Delhi (Registered with NITI Aayog, Govt. of India)







#### ONE WEEK ONLINE TRAINING COURSE ON BIOETHICS & GOOD CLINICAL PRACTICES (GCP)

# ABOUT UTTAR PRADESH UNIVERSITY OF MEDICAL SCIENCES:

The Uttar Pradesh University of Medical Sciences, is a medical college, hospital, and medical research institution in Saifai, Etawah, U.P., India., running with full-fledged Medical College, Dental College (postgraduate), Paramedical College, Nursing College, Pharmacy College, Multi-Specialty 850 bedded hospital, 150 bedded trauma and burn center and 500 bedded Super Specialty hospital. The Medical University is transforming in order to support clinical research and offer better patient care.

### ABOUT DEPARTMENT OF HEALTH RESEARCH-MULTIDISCIPLINARY RESEARCH UNIT:

Established under aegis of DHR, MoHFW, Govt. of India at Uttar Pradesh University of Medical Sciences, Saifai, Etawah (206130). The Unit is to perform cutting-edge research in the field of health sciences, with a special emphasis on patient care in noncommunicable diseases, and provide a central instrumentation facility and research environment for faculties and SR/JR PG students to choose and carry out their top research priorities on their own premises.







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### **ABOUT RESILIENT FOUNDATION :**

Resilient Foundation for Academic Innovation & Scientific Research, New Delhi is a not-for-profit organization registered under section 8 of the companies' act 2013, India. The organization is established having primary aim to promote academic & research activities through knowledge sharing, innovation, skill development and capacity building in various sectors like academia, industry and government for betterment of society. For more details please visit https://theresilientfoundation.org/

### **ABOUT THE TRAINING COURSE:**

Good Clinical Practices (GCP) refer to a set of ethical and scientific quality standards for designing, recording and reporting trials that involve the participation of human subjects. GCP guidelines define the responsibilities of sponsors, investigators, and ethics committees in conducting clinical research. These guidelines are essential to maintaining the rights, safety, and well -being of clinical trial participants and ensuring the validity and reliability of clinical trial data. Everyone involved in the conduct of clinical research must be competent to perform their tasks, qualified by education, training and experience. This training course will cover all aspects of GCP guidelines and ethical issues in conducting clinical research.





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## **OBJECTIVE OF THE TRAINING COURSE:**

An understanding of GCP is prerequisite for anyone carrying out, or involved in, clinical research and clinical trials.

Members of ethics committees, institutional review boards (IRBs), or research ethics boards (REBs) who review and approve clinical trial protocols should have a solid understanding of GCP principles. GCP training helps them evaluate the ethical aspects of proposed trials, ensuring participant rights, safety, and welfare.

# WHY THIS TRAINING COURSE IS IMPORTANT FOR YOU?

- GCP training course is now essential for all PG students and teaching faculties as per recent NMC Guidelines.
- ICMR guideline also states that the members of IRB and Independent Ethics Committee (IEC) should have GCP training.

### THE EXPECTED OUTCOME OF THE TRAINING COURSE:

- Empower clinicians and researchers about basics of GCP and aware about current regulation and guidelines in India for Clinical Trials
- understand the key components of GCP including informed consent research protocol
- ensure the data management and quality assurance policies and practices involved in clinical research







# PROGRAM SCHEDULE TIMING: 06:30PM-08:00PM

Day	Topics
Day 1 22 August, 2025	<ul> <li>Introduction to GCP</li> <li>Guidelines in India and WHO GCP</li> <li>Consequences of GCP non-compliance</li> </ul>
Day 2 23 August, 2025	<ul> <li>Roles and Responsibilities:</li> <li>Sponsor, Investigator and Ethics committee</li> <li>Informed Consent process</li> </ul>
Day 3 24 August, 2025	Development of Research protocol
Day 4 25 August, 2025	<ul> <li>Confidentiality and Privacy</li> <li>Documentation and Record Keening</li> </ul>
Day 5 26 August, 2025	Role of Bioethics in Research
Day 6 27 August, 2025	<ul> <li>Safety and Adverse Events, Monitoring of clinical trial participants</li> </ul>
Day 7 28 August, 2025	• Role of Regulatory Bodies







# METHODOLOGY

- Online live classes by eminent experts from reputed organizations of the country
- Participatory discussion with Q&A
- Demonstrations
- Recordings of the all sessions will be provided to all registered participants

# NATURE OF PARTICIPANTS

The participants will be MBBS/MD/MS Doctors, Nurses, Clinical research coordinators, Pharmacists, Allied health professionals, Ethics Committee Members or any one working in the area of clinical re search.

# **DURATION & TIME**

One Week (22 - 28 August, 2025) Timing : 06:30 PM To 08:00 PM







# **REGISTRATION PROCESS:**

Registration Fee for all Participants = Rs. 600/-

### **Registration Link**

https://theresilientfoundation.org/current-events/

# **TRAINING RULE**

### Highlights of the Training Course:

- Registered participants will get e-certificates
- Video recording of all sessions will be provided to all registered participants.
- Workshop by Subject Experts from reputed Institute & Universities
- Workshop will be on the Zoom meeting platform.

For Further Queries, Please Mail Us At : <u>info@resilientfoundation.in</u> or call at +91-8840112492.

Last Date of Registration: 22 August, 2025 (Till 4:00 PM)





# **ABOUT RESOURCE PERSONS**

Dr. Ravinder Singh, is medical graduate with doctorate training in public health. He is looking after the areas of mental health, disability, rehabilitation and assistive technologies at ICMR Headquarters (Department of Health Research, Ministry of Health & Family Welfare, Government of India), New Delhi. He completed his Ph.D. (Public Health) on Adolescent Stress from Jawaharlal Nehru University in 2013. He has experience of more than two decades in health research.

**Prof (Dr) Sunil Raina, is the Professor & Head, Department of Community Medicine at** Dr. RP Government Medical College, Tanda (Himachal Pradesh), India. He is also the Director of the Centre for Advancing Tobacco Control in Himachal Pradesh (CATCH) and adjunct Professor for Manipal Academy of Higher Education (MAHE), Karnataka, India and Father Muller Research Centre, Manglore. He is co-faculty at New England Complex Systems Institute (NECSI) Dr. Raina was a member Government of India panel on High Altitude Medicine and expert member C- 20 panel of G-20 Summit which was chaired by India in the year 2023. He is expert advisor to the Indian Council of Medical Research (ICMR)-Centre for Non Communicable diseases Kolkata, India and Member Scientific Advisory Committee, National Institute of Implementation Research (ICMR-NIIRNCD), Government of India.

Dr. Kanica Kaushal, is an accomplished medical professional with expertise in public health and is currently working as an Associate Professor, Department of Clinical Research and Epidemiology atInstitute of Liver and Biliary Sciences (ILBS), New Delhi. She has worked at prestigious institutions and gained recognition from national and international organizations. Dr Kanica has spearheaded innovative public health projects at the ILBS, New Delhi, and is actively involved in implementing national guidelines for Non-Alcoholic Fatty Liver Disease (NAFLD) in India. She is also dedicated to creating awareness and challenging stigma related to Hepatitis B through various campaigns like EMPATHY (Empowering People Against Hepatitis) (https://theempathycampaign.com/), WOMB (Winning Over Mothers with Hepatitis B) and regarding Fatty Liver through nationwide initiatives like SMilES (Stronger India through a Million Health Edudated Students) and IMELD (Indian Metabolic and Liver Diseases).







# ORGANISING TEAM OF THE TRAINING COURSE Chief Patron



**Dr. P. K Jain** Vice Chancellor, U P University of Medical Sciences, Saifai, Etawah, U. P

### **CO- PATRONS**



Dr. Ramakant Yadav Pro Vice Chancellor U P University of Medical Sciences, Saifai Etawah, U. P



Dr. Adesh Kumar Dean U P University of Medical Sciences, Saifai Etawah, U. P

Dr. S.P.Singh M S U P University of Medical Sciences, Saifai Etawah, U. P



Dr. Ravinder Singh Senior Scientist ICMR, New Delhi



**Prof. Karan P.Singh** School of Medicine, University of Texas, USA

#### **ORGANIZING SECRETARY**



Dr.D.K. Yadav Assistant Professor NIHFW,New Delhi

#### CONVENER



Dr. SushilKumarShukla (Nodal Officer, MRU) Professor U P University of Medical Sciences, Saifai Etawah, U. P.