About the Institute

The National Institute of Health & Family Welfare is a premier autonomous Institute, funded by the Ministry of Health and Family Welfare, Government of India. It has kept pace with the new thinking and substantially contributed to the health manpower development in the country.

NIHFW serves as an apex 'technical institute' as well as a 'think tank' to promote national health and family welfare programmes in the country through education and training, research and evaluation, consultancy & advisory services, specialized projects, etc.

The Department of Epidemiology of the institute are organizing an **offline** 6th training course on **"Bioethics and Good Clinical Practices"**. In last one year around 600 participants have been trained in GCP and Bioethics.

Last date for receiving nominations/ Filling of Registration Form

18th July, 2025

Link of Registration Form

https://forms.gle/KVZKJxZvxMhznKpk9

Course Coordinating Team

Course Coordinator : Dr. Rajesh Ranjan

Course Co-coordinator : Dr. Meerambika Mahapatro

Course Associates : Mr. Lakhanlal Meena
Ms. Bhawna Kathuria
Mr. Vishal Drall

Further Correspondence to be addressed to:

Course Coordinator
Dr. Rajesh Ranjan
HoD, Department of Epidemiology

The National Institute of Health and Family Welfare
Munirka, New Delhi-110 067

Email: epid@nihfw.org

Phone: 011-2616 5959/2 616 6441/ 2618 8485/ 2610 7773
Ext: 371/ 373/ 359

Website: www.nihfw.ac.in

6th Training Course on Bioethics and Good Clinical Practices

4th – 6th August, 2025

आरोग्यम् सुखसम्पदा

Department of Epidemiology
The National Institute of Health and Family Welfare,
Baba Gangnath Marg, Munirka,
New Delhi - 110067

Phones: 011-26165959/ 26166441/ 26185696/ 26107773,
Fax: 91-11-26101623
Website: www.nihfw.ac.in

Introduction

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. Bioethics is important as medical policies and patients rights legislations are ever changing and health care systems function differently than before.

Compliance to ethical principles as well is inherent and essential component of scientific and ethical conduct of clinical research in India to ensure the right, safety and well-being of selfless participants. It is now essential for all PG students and teaching faculties as per recent NMC Guidelines.

A short duration (3 working days) training for MBBS, MD/MS Doctors, Nurses, Clinical research coordinators, Pharmacists, Allied health professionals, Ethics Committee Members has been developed to provide them a comprehensive understanding of GCP guidelines, principles and practices, roles and responsibilities of sponsors, investigators, and ethics committees, key components of GCP, adverse event reporting and management, research ethics and informed consent. The course aims to provide participants with the knowledge necessary to conduct high-quality clinical research that meets regulatory requirements and produces reliable data.

General Objective

To train strengthen and empower participants to ensure that they understand scientific aspects, regulatory norms, ethical concern, conduct and reporting of clinical research that will be of uniform nature and meets national and international quality standards.

Specific Objectives

This course will help to:

- Empower clinicians and researchers about basics of GCP and aware about current regulation and guidelines in India for Clinical Trials
- Describe the roles and responsibilities of IRB/ IEC, sponsors, investigators and monitors
- 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

Course Contents

- Overview of GCP & GCP Guidelines in India and WHO's GCP Guidelines
- Overview of NDCT Rules 2019
- Research protocol development
- Roles and Responsibilities: Sponsor, Investigator, Monitor, CRO & SMO
- Consequences of GCP non-compliance
- Confidentiality and Privacy, Safety and Adverse Events, Monitoring of clinical trial participants
- Quality assurance & Quality Control
- Data handling and Record Keeping
- Evolution of Bioethics & its importance in clinical research
- Case studies and group activity on Bioethics
- Research Ethics & Informed Consent
- IEC registration and function
- Oppression of ethics and safety of clinical research participants

Methodology

The Participatory approach will be adopted throughout the course comprising of:-

- Lecture cum Discussion
- Case Studies
- Role play and theatre

Duration

3 days (4th - 6th August, 2025) 9.00 am –5.30 pm.

Nature of Participants

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

Training Outcome

The expected outcome of the course is improvement in ethical practices in research.

Course Fee

There will be a course fee of Rs. 3000/- per participant (excluding GST) need to be paid through online banking. The bank details are:

Name of the Beneficiary	:	Director, NIHFW
Bank Name & Branch	:	SBI, NIHFW, Munirka, New Delhi-110067
Saving Account No.	:	43901234540
IFSC Code No.	:	SBIN0001624
MICR Code No.	:	110002056

The course fee of Rs. 3,000/- includes training kit, tea/ snacks and working lunch during the course.