## 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 11th training course on **"Bioethics and Good Clinical Practices"**.

## Last date for receiving nominations/ Filling of Registration Form

23rd November, 2026

**Link of Registration Form**

**https://forms.gle/Ec6TWoXPHd4EPt5M9**




## 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:

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# 11th Training Course on BIOETHICS AND GOOD CLINICAL PRACTICES

## 07th – 09th December, 2026



**Department of Epidemiology**
**The National Institute of Health and Family Welfare,**
**Baba Gangnath Marg, Munirka,**
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## 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.

Everyone involved in the conduct of clinical research must be competent to perform their tasks, qualified by education, training and experience. An understanding of GCP and Bioethics is prerequisite for anyone carrying out, or involved in, clinical research and clinical trials. 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 clinicians, research coordinators and Ethics Committee members 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

- Introduction to GCP and its Guidelines in India and WHO GCP Guidelines
- Consequences of GCP non-compliance
- Roles and Responsibilities: Sponsor, Investigator and Monitor
- Research Ethics & Informed Consent
- Quality assurance & Quality Control
- Data handling and Record Keeping
- Overview of new drugs and clinical trial regulations in India
- Confidentiality and Privacy & Safety and Adverse Events, Monitoring of clinical trial participants
- Issues related with Research protocol development
- Role of CRO & SMO
- Case studies and group activity on ethics
- IEC registration and function

## Methodology

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

- Lecture cum Discussion and Case Studies (Sample case studies) will be discussed.

## Duration

3 days (07th - 09th December, 2026) 9.00 am –5.30 pm.

## 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 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 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 |
| Account No. | : | 43901234540 |
| IFSC Code No. | : | SBIN0001624 |
| MICR Code No. | : | 110002056 |

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