

Strengthening Research Integrity: Workshop on Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Research Ethics for Postgraduate Students.

Topic: Workshop on Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and Ethics

Date: 13th March, 2026

Venue: Sushruta LT-3, Himalayan Institute of medical Sciences

Organized By: Dr Nikku Yadav & Team, Himalayan Institute of medical Sciences, Swami Rama Himalayan University

Speakers: Dr. Nikku Yadav, Incharge, Department of Clinical Research

Prof. D.C. Dhasmana, Professor, Department of Pharmacology

Prof. AK Srivastava, HOD, Department of Community Medicine

Dr. Richa Sinha, Assistant Professor, Department of Pharmacology

Dr. Harvinder Chhabra, Assistant Professor, Department of FMT

Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research

Mr. Abhinav Bahuguna, Lecturer, Department of Clinical Research and Biostatistics

No. of Participants: 112 PG Students (MD, MD, DM, MCh)

Introduction: The workshop on Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and Ethics was conducted on 13th March 2026 at HIMS. The objective of the workshop was to enhance participants' understanding of regulatory guidelines and ethical considerations in clinical and laboratory research. The event brought together healthcare professionals, researchers, and students to discuss best practices, regulatory requirements, and ethical challenges in the field of biomedical research.

Objectives of the Workshop

- To provide an overview of GCP and its role in clinical trials.
- To highlight the principles and significance of GLP in laboratory research.
- To discuss ethical considerations in research involving human participants.
- To familiarize participants with national and international regulatory guidelines.
- To promote compliance with ethical standards in research.
- To introduce the basics of biostatistics in research.

Sessions and Key Discussions

The session began with a Pretest which consisted of 20 questions to evaluate the level of knowledge of medical postgraduate students.

Session 1: New Drug discovery and development

Speaker: Dr. Nikku Yadav, Incharge, Department of Clinical Research

Session Highlights:

- Discovery & Preclinical Testing – Identify drug targets, screen compounds, and test in animals for safety and efficacy.
- Phase 1 Clinical Trials – Small-scale human testing to determine safety and dosage.
- Phase 2 Clinical Trials – Medium-scale patient trials to assess efficacy and side effects.
- Phase 3 Clinical Trials – Large-scale trials to confirm effectiveness and compare with existing treatments.
- Approval & Post-Market Surveillance – Regulatory review, market release, and long-term safety monitoring.

Session 2: Epidemiological study designs

Speaker: Prof. AK Srivastava, HOD, Department of Community Medicine

Session Highlights:

Epidemiological study designs are broadly classified into **observational** and **experimental** studies:

Observational Studies (No intervention by researchers)

Descriptive Studies (Describe patterns of disease occurrence)

- *Case Report & Case Series* – Detailed report on a single case or group of cases.
- *Cross-Sectional Study* – Measures disease and exposure at a single point in time (snapshot).

Analytical Studies (Assess relationships between exposure and outcome)

- *Case-Control Study* – Compares individuals with a disease (cases) to those without (controls) to identify past exposures.
- *Cohort Study* – Follows exposed and unexposed groups over time to compare disease incidence.
 1. Prospective Cohort
 2. Retrospective Cohort

Experimental Studies (Researcher intervenes)

- **Randomized Controlled Trial (RCT)** – Participants are randomly assigned to treatment or control groups to test interventions.
- **Quasi-Experimental Study** – Similar to RCT but lacks full randomization.
- Each design has strengths and limitations, chosen based on research objectives and feasibility.

Session 3: Good Clinical Practice (GCP) Principles

Speaker: Dr. Richa Sinha

Session Highlights:

- Ethical Conduct of Clinical Trials – Ensuring that clinical trials are conducted according to ethical principles that protect the rights, safety, and well-being of participants.
- Scientific Quality and Integrity – Clinical trials must be scientifically sound, properly designed, and accurately documented.
- Informed Consent – Participants must voluntarily participate in the study after receiving complete information about the study objectives, risks, benefits, and procedures.
- Roles and Responsibilities – Clear responsibilities of investigators, sponsors, and ethics committees in conducting and monitoring clinical trials.
- Data Accuracy and Confidentiality – Ensuring proper recording, handling, and storage of data while maintaining participant confidentiality.
- Regulatory Compliance – Adherence to national and international guidelines such as ICH-GCP and regulatory authorities to maintain quality and credibility in clinical research.

Session 4: Basics of Biostatistics Research

Speaker: Mr. Abhinav Bahuguna, Lecturer, Department of Clinical Research and Biostatistics

Session Highlights:

- Study Design & Data Collection
- Types of Data
- Descriptive Statistics (Summarizing Data)
- Inferential Statistics (Drawing Conclusions)
- Bias & Error Considerations

Session 5: Professional Ethics- Code of conduct in medical practice

Speaker: Dr. Harvinder Chhabra , Assistant Professor, Department of FMT

Session Highlights:

- Patient Welfare & Autonomy
- Competence & Continuous Learning
- Honesty & Integrity
- Respect & Non-Discrimination
- Accountability & Legal Compliance

Session 6: Human Research Ethics: (NDCT 2019; Sponsor, Investigator's and IEC responsibilities, Informed Consent process)

Speaker: Prof. D.C. Dhasmana, Professor, Department of Pharmacology

Session Highlights:

Human Research Ethics (New Drugs and Clinical Trials Rules, 2019 - India)

1. Ethical Principles in Human Research

- Protect rights, safety, and well-being of participants.
- Ensure scientific validity and ethical integrity.
- Maintain transparency and regulatory compliance.

2. Responsibilities of Key Stakeholders

- Sponsor (Funding & Oversight)
- Investigator (Conduct & Compliance)
- Institutional Ethics Committee (IEC) (Approval & Monitoring)

3. Informed Consent Process

- Participants must receive clear, comprehensive information on study purpose, risks, benefits, and voluntary participation.
- Consent must be written, voluntary, and informed, ensuring participant understanding.
- Special protection for vulnerable populations (e.g., minors, pregnant women).
- Ongoing consent required for any protocol changes.
- Adhering to NDCT 2019 ensures ethical, safe, and responsible human research practices.

Session 7: Indian GCP and GLP Guidelines

Speaker: Dr. Manisha Sharma, Assistant Professor, Department of Clinical Research

Session Highlights:

Indian GCP and GLP Guidelines

1. Indian Good Clinical Practice (GCP) Guidelines

(Issued by CDSCO, aligned with ICH-GCP & Schedule Y of Drugs and Cosmetics Rules, 1945)

Key Principles:

- Ethical Conduct: Protect participant rights, safety, and well-being.
- Scientific Integrity: Trials must be methodologically sound and properly documented.
- Informed Consent: Participants must voluntarily agree after receiving full study details.
- Confidentiality: Patient data must be kept private and secure.
- Investigator's Responsibility: Conduct trials as per protocol and report adverse events.
- Regulatory Compliance: Follow DCGI (Drug Controller General of India) approvals and guidelines.
- Post-Trial Access: Participants should receive necessary care after the trial.

Indian Good Laboratory Practice (GLP) Guidelines

(Issued by NGCMA - National GLP Compliance Monitoring Authority, under DST)

Key Principles:

- **Quality Assurance:** Ensure reliability and reproducibility of non-clinical laboratory studies.
- **Study Planning & Conduct:** Clear protocols, trained personnel, and validated procedures.
- **Data Integrity:** Maintain accurate, traceable, and secure study records.
- **Facility & Equipment Standards:** Properly maintained labs, calibrated instruments, and controlled environments.
- **Test Item Control:** Document handling, storage, and stability of test substances.
- **Reporting & Archiving:** Transparent reporting and long-term record maintenance.

Interactive Session

Following the lecture, an engaging post test session was held where students had the opportunity to evaluate themselves with the help of an online feedback test.

Conclusion and Recommendations The workshop successfully enhanced participants' understanding of GCP, GLP, and ethical research principles. It was recommended that institutions implement continuous education programs and strengthen regulatory compliance frameworks. Participants also emphasized the need for interdisciplinary collaboration to uphold the highest standards in research and clinical practices.

