

**Department of Clinical Research  
Himalayan Institute of Medical Sciences  
SWAMI RAMA HIMALAYAN UNIVERSITY**

**WORKSHOP REPORT ON GOOD CLINICAL PRACTICES (GCP), GOOD LABORATORY PRACTICES (GLP), AND ETHICS**

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

**Date:** 26<sup>th</sup> March, 2025, 9.00-1.00 PM

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

**Organized By:** Department of Clinical Research, Himalayan Institute of medical Sciences, SRHU

**Workshop Co-Ordinator:** Dr Nikku Yadav, Incharge, Department of Clinical Research

**Speakers:** Prof. D.C. Dhasmana, Professor, Department of Pharmacology

Dr. Taruna Sharma, HOD, Department of Pharmacology

Dr. Pragya Tripathi, Assistant Professor, Department of FMT

Prof. AK Srivastava, HOD, Department of Community Medicine

Dr. Nikku Yadav, Incharge, Department of Clinical Research

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

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

**No. of Participants:** 117 PG Students

**Introduction:** The workshop on Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and Ethics was conducted on 26<sup>th</sup> March 2025 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.

#### **Sessions and Key Discussions**

The workshop was began with a Pretest assessment which consisted of 20 questions to evaluate the level of knowledge of students about Good Clinical Practices (GCP), Good Laboratory Practices (GLP, And Ethics

## 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: Principles of GCP:**

**Speaker 3: Dr Taruna Sharma, HOD & Professor, Department of Pharmacology**

#### **Session Highlights:**

- Principles of GCP
- Role of GCP in research
- Importance of GCP

### **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. Pragya Tripathi, 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.

**Role play: Study Start Up (Regulatory Trials):** Role plays were performed by MSc. Clinical Research students, and Clinical Research Associates from our Clinical Trial Centre, CRI, SRHU.

### 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.



4/4/25

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