

Shanghai Huashan Hospital, Fudan University
UNICEF/UNDP/World Bank/WHO Special Program for Research and Training in Tropical
Disease (WHO TDR)
Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP)

**GOOD CLINICAL PRACTICE & HEALTH RESEARCH ETHICS
TRAINING CENTER**

**A Training Workshop on
Principles of Good Clinical Practice and Research Ethics**

Shanghai, China
11-13 Dec, 2007

Objective:

To provide the investigators and ethics committee members with a comprehensive understanding of GCP principles, ethical considerations in health research involving human subjects and the application of scientific and ethical standards, which contribute to developing ethical review capacity and promoting the highest ethical and scientific standards in biomedical and behavioural research.

Faculties:	Dr. Juntra Karbwang	WHO TDR
	Ms. Jinqian Wang	Dep. of Science and Education of MOH in China
	Dr. Salome Vios	University of the Philippines College of Medicine
	Prof. Cristina E. Torres	FERCAP Coordinator
	Dr. Heidi Liu	FERCAP Medical Officer

Trainees: Investigators in clinical trial, Investigators in biomedical and behavioural research involving human subjects, Ethics committee members

Training Agenda

DAY 1

Dec 11

8:00-8:30

Registration

8:30-8:45

Course Orientation

PART I

Principles and Guidelines

8:45-9:30

History and Overview of International Guidelines in Research Ethics (Nuremberg, Helsinki, Belmont Report, CIOMS)

9:30 -10:15

Principles of Research Ethics

10:15-10:30

Break

10:30-11:15

History and Principles of GCP

PART II

Ethical Issues in Various Types of Research

11:15-12:30

Ethical Issues in Clinical Trials

12:30-1:00

Lunch

1:00-1:45

Ethical Issues in Epidemiological and Behavioural Research

1:45-2:30

Ethical Issues in International Health Research

2:30-3:15

Genetic Research & Use of Stored Samples

3:15-3:30

Break

3:30-4:00

Case Study

4:00-4:30

Case Presentation

DAY 2

Dec 12

PART III

Good Clinical Practice Guidelines

8:30-9:30

GCP Stakeholder Responsibilities

Role of Sponsor

Role of Clinical Monitor

Data Safety Monitoring Board

9:30-10:00

Role of Investigator

10:00-10:30

Role of IRB/IEC within GCP System

10:30-10:45

Break

10:45-11:45

National Guidelines for Ethical Review of Clinical Trials

11:45-12:30

WHO SIDCER Recognition Program and Training Network

12:30-1:00

Lunch

PART IV

Ethical Considerations in Protocol Preparation and Review

1:00-1:30

Ethical Considerations in Protocol Design and Conduct

1:30-2:00

Protecting Privacy and Confidentiality of Health information

2:00 -2:30

Conducting Research among Vulnerable Subjects

2:30-3:00

Management of Conflicts of Interests

3:15-3:30

Break

3:30-4:00

Risk/Benefit Assessment in Ethical Review

4:00-4:30

Elements of Informed Consent

DAY 3

Dec 13

PART V

IRB Operational Procedures

8:30 -9:00

WHO Operational Guidelines for Ethics Committees that Review Biomedical Research

9:00-9:30

Ethical Review Procedures

9:30-10:00

Submission requirements

10:00-10:30

Continuing Review and Monitoring Research

10:30-10:45

Break

10:45-11:45

Mock Review

11:45-12:00

Training Certificate

12:00-12:30

Conclusion