## การฝึกอบรมเชิงปฏิบัติการ หลักสูตรนานาชาติ เรื่อง Human Participant Protection and GCP Training

# (ร่วมกับจุฬาลงกรณ์มหาวิทยาลัย IHRP และ FERCAP)

## <u>DAY 1</u>

8:00-8:30	Registration
8:30-8:45	Opening
8:45-9:00	Course Orientation
9:00-9:30	History of Research Ethics - Origin of International Guidelines
	Nuremberg, Helsinki
9:30-10:15	Principles of Research Ethics Autonomy, Beneficence, Justice
10:15-10:30	Break
10:30-11:15	Ethical Issues in Conducting Research in Developing Countries
	CIOMS
11:15-12:00	Local Laws and Regulations, Applicable Local Requirements
12:00-13:00	Lunch
13:00-13:45	Conflict of Interest Issues
13:45-14:30	The Informed Consent Process
14:30-14:45	Break
14:45-15:30	Privacy and Confidentiality of Health Information
15:30-16:15	Group Discussion
16:15-17:00	Group Report

#### DAY 2

9:00-9:45	Research among Vulnerable Population: Prisoners, Employees &
	Students, Medically Vulnerable Groups, Fetuses & Children,
	Culturally Vulnerable Groups & Minorities, Economically -
	Disadvantaged
9:45-10:15	Risk/Benefit Assessment in Ethical Review
10:15-10:30	Break
10:30-11:15	Ethical Issues in Clinical Trials
11:15-12:00	Epidemiological and Behavioural Research
12:00-13:00	Lunch
13:00-13:45	Genetic Research & Stored Samples
13:45-14:30	Traditional and Alternative Medicine
15:00-15:45	Group Discussion
15:35-16:30	Group Report

### DAY 3

8:30-9:15	History and Principles of Good Clinical Practice
9:15-9:45	Role of Sponsor
9:45-10:15	Role of Clinical Monitor
10:15-10:30	Break
10:30-11:15	Data Safety Monitoring Board
11:15-12:00	Role of Investigator

12:00-13:00	Lunch
13:00-13:45	Role of IRB/IEC
13:45-14:30	WHO Operational Guidelines for Ethics Committees
14:30-15:15	SIDCER Recognition Program
15:15-15:45	Break
15:45-16:15	Group Discussion
16:15-17:00	Group Report
17.00	Certificate Awarding