

Chulalongkorn University, Thailand
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

Human Participant Protection and GCP Training

Bangkok, Thailand
3-5 March, 2008

DAY 1

8:00-8:30	Registration
8:30-8:45	Course Orientation
8:45-9:30	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
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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
14:30-15:00	Break
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

Faculties:

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