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

Ethical Review Committee SOP Training Workshop

Bangkok, Thailand
28-30 April, 2008

Day 1

8:30 – 9:00 Registration
9:00 – 9:30 SIDCER Recognition Program

9:00 – 9:45 Overview of SOPs
Preparing SOPs and Guidelines for Ethics Committees
- *Writing, Reviewing, Distributing and Amending Standard Operating Procedures for Ethics Committees*
- *Preparation of Guidelines*

9:45 – 10:00 Break
10:00 – 10:45 Constituting an IEC/IRB
- *Constituting an IEC/IRB*
- *Confidentiality / Conflict of Interest Agreements*
- *Training Personnel and IEC/IRB Members*
- *Selection of Independent Consultants*

10:45 – 11:15 Review Procedures and Forms (1)
- *Management of Protocol Submissions (Forms and Requirements)*
- *Expedited Review Issues and Procedures*

11:15 – 12:00 Review Procedures and Forms 2 (Full Board)
- *Initial Full Board Review of Submitted Protocols*
- *Review of New Medical Device Studies*
- *Use of Study Assessment Forms*

12:00 – 1:30 Lunch Break

1:30 – 2:15 Protocol Amendments, Continuing Review and End of Study Reports (Issues and Concerns)
- *Review of Resubmitted Protocols*
- *Review of Protocol Amendments*

- *Continuing Review of Study Protocols*
- *Review of Final Reports*

2:15 – 3:00 **Preparation of Review Meeting Agenda and Communication Records**
- *Agenda Preparation, Meeting Procedures and Minutes*
- *Emergency Meeting*
- *Communication Records*

3:15 – 3:30 **Break**

3:30 – 4:15 **Group Discussion (Case Study)**

4:15 – 5:00 **Case Discussion**

Day 2

9:00 – 9:45 **Topic 9– Managing Study Files**
- *Maintenance of Active Study Files*
- *Archiving and Retrieval of Documents*
- *Maintaining Confidentiality of IEC/IRB Documents*

9:45 – 10:00 **Break**

10:00 – 11:30 **Site Visit - Chulalongkorn Faculty of Medicine IRB**

Office Visit

Sign Confidentiality Agreement

Review of Files
- *Membership File*
- *Protocol File*
- *SAE File*
- *Agenda and Minutes*

11:30 – 12:00 **Preparation for Board Meeting Observation**

12:00 – 3:00 **Observation of Board Meeting**

3:00 – 5:00 **Analysis of Office Visit and Board Meeting**

Day 3

9:00 – 9:45 **Monitoring Protocol Implementation**
- *Non-Compliance/Violation Intervention*
- *Response to Participants' Requests*
- *Management of Study Termination*

9:45 – 10:00 **Break**

10:00 – 10:45 **Monitoring and Evaluation of Adverse Events**
Review of Serious Adverse Events (SAE) Reports

10:45 – 11:30 **Site Monitoring Visit**

11:30 – 12:00 **Maintaining an IEC/IRB Data Base**

12:00 – 1:30 **Lunch Break**

1:30 – 2:15 **Local Regulation and Regulatory Inspection**

2:15 – 2:30 **Break**

2:30 – 4:15 **IRB Roles: Chairman**
Secretary
Staff
Lay Member
IRB Committees

4:15 – 5:00 **Evaluating an IEC/IRB**
SIDCER ***Self Evaluation Tool***
External Evaluation and Audit

Faculties:

Dr. Yuppadee Jaorungrid	Thai FDA
Dr. Anek Aribarg	Faculty of Medicine, Chulalongkorn University
Prof. Sopit Thamaree	Faculty of Medicine, Chulalongkorn University
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