



FORUM FOR ETHICAL REVIEW COMMITTEES IN ASIA AND THE WESTERN PACIFIC REGION

Office: Department for the Development of Thai Traditional and Alternative Medicine
Ministry of Public Health
Tiwanon Road, Nonthaburi, Thailand 11000
Telefax: 662-951-0721 Website: <http://www.fercap-sidcer.org>

FERCAP Ethical Review Committee Standard Operating Procedure (SOP) Workshop

Host: Forum for Independent Review System in Taiwan (FIRST)

Date: March 28-29, 2005

Venue: The Chi Teh Building, 3rd Conference Room, Taipei Veterans General
Hospital, Taipei, Taiwan

Workshop Schedule

Day 1

- 8:00 – 8:45 Registration
- 8:45 – 9:00 Welcome Remarks and Workshop Orientation
Dr. Benjamin Kuo, FIRST
- 9:00 – 9:30 Preparing SOPs and Guidelines for IEC/IRB
Dr. Juntra Karbwang, WHO
- 9:30 – 10:00 Constituting an IEC/IRB
Dr. Suraidi Gunawan
- 10:00 – 10:30 Coffee Break
- 10:30 – 11:15 Workshop 1 – Analyzing Current IEC/IRB SOPs
- 11:15 – 12:00 Group Reports
- 12:00 – 1:00 Lunch Break
- 1:00 – 1:30 Review Requirements and Procedures
Dr. Cristina E. Torres
- 1:30 – 2:00 Protocol Amendments, Continuing Review, and End of Study
Requirements
Dr. Kesara Na Banchang
- 2:00 – 2:30 Coffee Break
- 2:30 – 3:15 Workshop 2 – SOP for Review Procedures
- 3:15 – 4:00 Group Reports
- 4:00 – 5:00 Open Forum: Discussion of Issues Dr. Emil Aligui

Day 2

- 8:00 – 8:30 Monitoring Protocol Implementation
Dr. Vasantha Muthuswamy
- 8:30 – 9:00 Monitoring Adverse Events and SAEs
Dr. Kenji Hirayana
- 9:00 – 9:30 Site Visits
Dr. Vichai Chokevivat
- 9:30 – 10:00 Coffee Break
- 10:00 – 10:45 Workshop 3 – Monitoring Research Protocol by IEC/IRBs
- 10:45 – 11:30 Group Report
- 11:30 – 12:00 Maintaining a Data Base
Mr. Wittaya Phanmuang
- 12:00 – 1:00 – Lunch Break

1:00 – 1:30	Preparation of Review Meeting Agenda and Communication Records	Dr. Sirinart Vasanvathana
1:30 – 2:00	Managing Active Study Files	Dr. Benjamin Kuo
2:00 – 2:30	Audit and Inspection of IEC/IRB	Dr. Ock Joo Kim
2:30 – 3:00	Coffee Break	
3:00 – 3:45	Workshop 4 – Managing an IRB	
3:45 – 4:15	Group Reports	
4:15 – 4:45	Open Forum	Dr. Anoja Fernando
4:45 – 5:00	Synthesis	Dr. Anoja Fernando
	Closing Remarks	Dr. Vichai Chokevivat

Qualifications of Workshop Participants:

1. Should be a FERCAP member
2. Should be an IEC/IRB member or staff
3. Should have undergone basic IEC/IRB training
4. Should bring a copy of SOP draft used by the IEC/IRB