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 Chokeevivat
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