Shanghai Huashan Hospital, Fudan University
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

Ethics Committee SOP Training Workshop

Shanghai, China
28-29 March 2008

Day 1

8:00 – 8:30	**Registration**
8;30 – 9:00	**SIDCER Recognition Program**
9:00 – 9:30	**Overview of SOPs**
	Preparing SOPs and Guidelines for Ethics Committees
	1.1 Writing, Reviewing, Distributing and Amending Standard Operating Procedures for Ethics Committees
	1.2. Preparation of Guidelines
9:30 – 10:00	**Constituting an IEC/IRB**
	2.1. Constituting an IEC/IRB
	2.2. Confidentiality / Conflict of Interest Agreements
	2.3. Training Personnel and IEC/IRB Members
	2.4. Selection of Independent Consultants
10:00 – 10:15	**Break**
10:15 – 11:00	**Review Procedures and Forms (1)**
	3.1. Management of Protocol Submissions (Forms and Requirements)
	3.2. Expedited Review Issues and Procedures
11:00 – 12:00	**Review Procedures and Forms 2 (Full Board Review)**
	3.3. Initial Full Board Review of Submitted Protocols
	3.4. Review of New Medical Device Studies
	3.5. Use of Study Assessment Forms
12:00 – 1:00	**Lunch Break**
1:30 – 5:00	**Site Visit - Changhai Hospital IRB**
	Office Visit
	Review of Files
	○ **Membership File**
	○ **Protocol File**
	○ **SAE File**
	○ **Agenda and Minutes**

Day 2

8:30 – 9:00	**Protocol Amendments, Continuing Review and End of Study Reports (Issues and Concerns)**
	4.1. Review of Resubmitted Protocols
	4.2. Review of Protocol Amendments
	4.3. Continuing Review of Study Protocols
	4.4. Review of Final Reports
9:00 – 9:30	**Monitoring Protocol Implementation**
	5.1. Non-Compliance/Violation Intervention
	5.2. Response to Participants' Requests
	5.3. Management of Study Termination
9:30 – 10:00	**Monitoring and Evaluation of Adverse Events**
	Review of Serious Adverse Events (SAE) Reports
10:00 – 10:30	**Break**
10:30 – 11:00	**Site Monitoring Visit**
11:00 - 11:30	**Preparation of Review Meeting Agenda and Communication Records**
	8.1. Agenda Preparation, Meeting Procedures and Minutes
	8.2. Emergency Meeting
	8.3. Communication Records
11:30 – 13:00	**Lunch**
13:00 – 13:30	**Topic 9– Managing Study Files**
	9.1. Maintenance of Active Study Files
	9.2. Archiving and Retrieval of Documents
	9.3. Maintaining Confidentiality of IEC/IRB's Documents
13:30 – 14:00	**Maintaining an IEC/IRB Data Base**
14:00 – 14:30	**Break**
14:30 – 16:00	**Mock Review**
16:30 – 17:00	**Closing Ceremonies**

Faculty:

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Dr. Jin Huang	Shanghai Changhai Hospital, Second Military Medical University
Prof. Cristina E. Torres	FERCAP Coordinator
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Dr. Heidi Liu	FERCAP Medical Officer