

**An International Conference on
Empowering Stakeholders in Health Research:
*Towards Developing an Ethics of Accountability and
Responsibility***

**Rama Gardens Convention Center
Bangkok, Thailand**

Pre Conference Training – November 23, 2008
Conference – November 24-25, 2008
FERCAP General Assembly – November 26, 2008
NAREC Meeting – November 26, 2008



**Forum for Ethical Review Committees
in Asia & the Western Pacific**

FERCAP/SIDCER



Strategic Initiative for Developing Capacity for Ethical Review

with support from

**UNICEF/ UNDP/ World Bank/ WHO Special Programme for Research and
Training in Tropical Diseases (TDR)**

In cooperation with

WHO SEARO & WPRO

**Institute for the Development of Human Research Protection (IHRP), Ministry of
Public Health, Thailand**

Forum for Ethical Review Committees in Thailand (FERCIT)

Introduction

International guidelines, including ICH-GCP, and national laws have been formulated to protect human participants in research. But much is dependent on the willingness of various stakeholders to uphold the highest ethical standards in the implementation of health research. It is important to empower the various stakeholders towards sustainable human participant protection programs.

This conference will examine various models, good practices and initiatives to ensure stakeholder empowerment in the conduct of health research. Reinforcing a system where stakeholders know and perform their duties and responsibilities contributes to credible data and the protection of the rights and safety of human participants. The whole empowerment cycle starts from protocol conception, development and approval, to ethical research implementation, monitoring and data management, until completion of final report.

Educating stakeholders about their roles and responsibilities is the first step towards empowerment. Supporting training and certification programs for investigators and ethics committee members can ensure qualified persons performing their functions. Setting up a responsible regulatory system to perform oversight functions reinforces good practices. Through plenary sessions and panel presentation, group discussions and area reports, the full range of empowerment issues and their contribution to human participant protection will be explored.

Objectives

General objective:

To explore and identify various models and mechanisms that will empower stakeholders in health research to contribute to human participant protection

Specific objectives:

- To describe the roles, responsibilities and initiatives by sponsors to empower stakeholders in health research
- To describe programs and initiatives to empower health research investigators for better human subject protection.
- To describe programs and initiatives to empower ethics review board committees to contribute to sustainable human participant protection programs
- To describe empowering models and practices of regulatory systems that may be replicated in various country settings
- To explore effective measures to empower participants in health research
- To identify gaps, facilitators and barriers to empowering systems in health research
- To suggest options and future direction of empowerment systems to maintain the highest ethical standards in health research
- To develop relevant Asian models of ethical research infrastructure that promote empowerment within the context of diverse Asian cultures alongside pluralistic socio-economic-politico systems.

Conference Methodology

The conference participants are drawn from the various sectors and disciplines involved in health research, mainly from Asia and the Western Pacific region and from other parts of the world. There are international representatives from national health authorities, ethics committees, researchers, research participants, academic institutions and the pharmaceutical industry.

Conference Sessions

There are various plenary sessions that will examine important topics for discussion. Panel discussions from area representatives will also be used for information exchange.

Conference Outcome

The conference should be able to contribute to better awareness, knowledge and practice about empowerment for better human participant protection.

FERCAP 2008 Conference Agenda

Day 1: November 24 2008

8:00 - 9:00 **Registration**

9:00 - 9:30 **Opening Ceremony**

Welcome Remarks

Introduction of Guests/ Delegation

*Vichai Chokevivat, Chairman, Forum for Ethical Review Committees in
Asia & the Western Pacific (FERCAP), IHRP*

9:30 – 10:30 **Plenary Session 1: Developing an Empowerment Framework in
Health Research**

Chairpersons: Vichai Chokevivat, Chairman, FERCAP
Suriadi Gunawan, Member, FERCAP Steering Committee (Indonesia)

**Defining Stakeholder Responsibilities: Towards Implementing a
Duty Based Ethics**

Greg Koski, SIDCER Advisory Board Chair

Defining Empowerment and its Application to Health Research

Juntra Karbwang, WHO-TDR

**Promoting Professional Excellence and Ethical Dependability:
Towards Leadership in Health Research:**

Chitr Sitthi-amorn, St. Louis Hospital, Thailand

Sustaining Networks to Empower Stakeholders in Health Research

Steven Wayling, WHO-TDR

Open Forum

10:30 - 11:00 **Tea and Coffee Break**

11:00 - 12:30 **Plenary Session 2: Improving Regulatory Oversight to Protect
Human Participants in Health Research**

Chairpersons: Ock-joo Kim, FERCAP Steering Committee Member
Aneck Aribarg, Joint Research Ethics Committee Chair, Thailand

**Regulatory Oversight through Human Research Protection
Programs**

Melody Lin, US Office for Human Research Protection

**Origin and Development of Chinese GCP and Challenges to Its
Implementation**

*Hejian Zou, Vice President, Shanghai Huashan Hospital, Fudan
University, China*

**Strengthening the Clinical Trial Authority of the Thai Food and
Drug Administration**

Dr. Yuppadee Javroongrit, Assistant Director, Thai FDA

**European Union Initiative towards Empowering Regulatory
Agencies in the Philippines**

Klara Tioskci, European Union Consultant

Use of Law, Regulation and Guidelines for Ethical Health Research

Chung-Liang Shih, Director General, Taiwan Bureau of Medical Affairs

Open Forum

12:30 -13:30 Lunch Break

**13:30 – 14:30 Panel Discussion 1: Sponsor Initiatives towards Empowerment of
Stakeholders in Health Research**

Chairpersons: Benjamin Kuo, Secretary General, Joint Institutional Review Board of
Taiwan and FERCAP Vice Chair
Aphornpirom Ketupanya, FERCIT Chair

**Promoting Human Subject Protection through the Risk
Management Approach**

Beat Widler, Roche Audit

Responsible Clinical Monitoring of Research Implementation

*Fe Esperanza Espino, Philippine Research Institute for Tropical
Medicine*

**Developing an Ethical Culture in Research through an Institutional
Regulatory Compliance Office**

*Sukanya Linpisarn, Research Institute for Tropical Medicine,
Chiangmai University*

**Upgrading the Research Infrastructure through Good Clinical
Laboratory Practice**

Varalakshmi Elango, India

Open Forum

14:30 - 15:00 Coffee Break

15:00 – 17:00 Panel Discussion 2: Empowering Investigators for Ethical Health Research

Chairpersons: Vasantha Muthuswamy, Former Senior Deputy Director General,
Indian Council for Medical Research and FERCAP Secretary
Kenji Hirayama, Nagasaki University Institute of Tropical Medicine

Protecting Participants in Oncology Research

Jorge Ignacio, Philippine General Hospital

Improving Informed Consent Procedures in HPV Study among Adolescents

Ricardo Manalastas, University of the Philippines College of Medicine

Forming Culture Sensitive Research Teams

Dr. Shuba Kumar, Samarth, India

Investigator Responsibilities in Conducting a Schistosomiasis Protocol in a Community Setting

Vicente Belizario, Jr., National Institutes of Health, University of the Philippines Manila

Certification for Ethics in Research Proficiency

Hwei ling Lee, National Cheng Kung University, Taiwan

Open Forum

18:30 Welcome Dinner

Day 2: Thursday, 25 November 2008

8:30 - 10:00 Panel Discussion 3: Empowering Ethics Committees towards Encouraging Responsible Behavior

Chairperson: Marita Reyes, Philippine Health Research Ethics Board
Suriadi Gunawan, FERCAP Steering Committee

Promoting Safety of Human Participants through Better SAE Management

Bradley Waite, Western Institutional Review Board

Regulatory Inspection and Quality Improvement of Korean IRBs
Young Mo Koo, Asan Medical Center, Korea

**Collective Action by Ethics Review Committees to Encourage
Responsible Behavior**
Vajira H. W. Dissanayake, University of Colombo

Role of Lay Person in a Research Ethics Committee
Felicidad Romuldez, Research Institute for Tropical Medicine

10:00 – 10:30 Coffee/Tea Break

**10:30 – 12:00 Panel Discussion 4: Understanding and Empowering the
Community and Research Participants**

Chairperson: Xiuquin Wang, FERCAP Steering Committee Member
Sopit Thamaree, Joint Research Ethics Committee, Thailand

**Community Advisory Groups: Can they facilitate ethical research
in clinical trials?**
Anant Bhan, EC Member, University of Pune, India

Community Participation in Accident Prevention among Children
*Orapin Chaipayom, College of Public Health Sciences, Chulalongkorn
University*

**Demographic Factors that Influence Understanding of Clinical
Trials and Research Ethics**
*Duk Yoon Kim, Im Hee Shin, Sang Gyung Kim, Oh Dae Kwon, Daegu
Catholic University, Korea*

**Formulating Guidelines for the Formation of Community Advisory
Boards for Ethical Research**
Nusara Thaitawat, USAMC-AFRIMS

12:00-13:30 Lunch Break

13:30 - 15:30 Group Discussion: Reports from FERCAP Area Representatives

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Empowering Stakeholders in the Asia Pacific Region

Chairperson: Anoja Fernando, Member, FERCAP Steering Committee, Sri Lanka
Ong-arj Viputsiri, WHO SEARO

Reports from: Representatives from Australia, Cambodia, India,
Indonesia, Japan, Korea, Laos, Malaysia, Mongolia, Myanmar, Nepal,
Peoples Republic of China, Philippines, Singapore, Sri Lanka, Taiwan,
Thailand, Vietnam

15:30-16:00 Coffee Break

16:00- 17:00 Presentations of Group Reports/ Resolutions – Group Panel Chairs

17:00 – 17:15 Closing Ceremonies

*Vichai Chokevivat, Chairman, Forum for Ethical Review Committees in
Asia & the Western Pacific (FERCAP)*

Pre-Conference Training
Managing an IRB for GCP Inspection/ Audit
1:00 – 5:00 pm
November 23, 2008

Agenda

- 1:00 – 1:30 – Registration**
1:30 – 2:15 – What is a GCP Inspection? What is a GCP Audit?
Allan Johansen
2:15 – 3:00 IRB Compliance with Regulations
Bradley Waite
3:00 – 3:30 Break
3:30 – 4:15 GCP Related Issues for IRB Management
Allan Johansen
4:15 – 5:00 Quality Management of IRBs
Juntra Karbwang

FERCAP General Assembly
9:00 – 12:00
November 26, 2008

Agenda

- 9:00 – 9:30 FERCAP 2008 Report**
Vichai Chokevivat
9:30 – 10:00 Report from Network of Asian Recognized IRBs (NAREC)
Chih-Shung Wong
10:00 – 11:30 Awarding of 2008 Recognition Plaques to IRBs
11:30 – 11:45 FERCAP Treasurer's Report
Kesara na Banchang
11:45 – 12:00 FERCAP Plans for 2009
Vichai Chokevivat
12:00 – 13:30
13:30 – 15:00 NAREC Meeting