

An International Conference on  
Transparency and Accountability in Health Research: *Towards  
an Ethics of Responsibility in Human Subject Protection*

in

**Phuket, Thailand**

29-30 November 2006  
**FERCAP General Assembly – 1 December 2006**



Forum for Ethical Review Committees  
in Asia & the Western Pacific

**FERCAP/SIDCER**



Strategic Initiative for Developing Capacity for Ethical  
Review

with support from

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Training in Tropical Diseases (TDR)

## **Introduction**

International guidelines and national laws have been formulated to protect human subjects in research. But the implementation of such documents is dependent on the willingness of various stakeholders to uphold the highest standards of integrity, accountability and transparency in the implementation of health research. The intent to uphold the highest standards of research should also be reinforced through the creation of systems in the various stages of the research process.

This conference will examine the various paradigms to define the roles and responsibilities of various research stakeholders including national health authorities, sponsors, investigators, editors and their relationship with ethics committees to ensure accountability and transparency in research. Through plenary and parallel sessions, group discussions and country reports, the full range of the system to ensure accountability and transparency is explored.

## **Objectives**

The primary objective of the Conference is to describe the roles and responsibilities of various research stakeholders to ensure accountability and responsible behaviour in the performance of their tasks in order to develop and improve the ethical framework for research and further ensure the protection of research participants and their communities.

In support of this aim, the conference also has the following specific objectives:

- to describe and compare the roles of and responsibilities of various research stakeholders related to the creation of an ethical infrastructure that supports accountability and transparency in the Asian and Western Pacific region;
- to examine the impact of current international guidelines to make research procedures more transparent;
- to identify and share best practices to address problems and barriers in creating accountable and transparent health research systems that protect human subjects and research participants;
- to consider best practices in research ethics against a background of
  - clear-cut and relevant guidelines and policies related to research ethics;
  - value sharing among various research stakeholders;
  - synergy among major international, regional and national health decision makers;
  - effective working relationships among important research stakeholders and Ethics Committees;
- to develop a relevant Asian model of an ethical research infrastructure that encourages accountable and transparent health research policies within the context of diverse Asian cultures and religions alongside pluralistic socio-economic and political systems.

## **Conference Methodology**

The conference participants are drawn from the various sectors and disciplines involved in health research. The participants are from Asia and the Western Pacific regions, as well as invited international guests: representatives of national health

authorities, ethics committees, researchers and their institutions, and the bio-pharma industry.

### **Conference Sessions**

The conference is composed of plenary sessions for the examination of critical topics and information exchange. These plenary sessions are supported by working groups where specific issues are explored in-depth and position papers developed.

### **Conference Outcome**

The primary outcome of the conference is the development of a position paper on the potential contribution of Asian and Western Pacific governments to national standards for Good Ethical Review Practice.

## FERCAP 2006 Conference Agenda

### Draft Program

#### Day 1: Wednesday, 29 November 2006

- 8:00 – 9:00 Registration
- 9:00 - 9:10 **Welcome Address: Establishing Research Objectives for Public Accountability of Health Research**  
*Suchai Charoenratanakul, Deputy Prime Minister of Thailand*
- Plenary Session 1: Proposing a Framework for Accountability and Transparency in Biomedical Research**
- Chairpersons: Vichai Chokevivat, Chairman, FERCAP  
Suriadi Gunawan, Member, FERCAP Steering Committee (Indonesia)
- 9:10 – 9:20 **Introduction of Guests**  
**Conference Overview**  
*Vichai Chokevivat, Chairman, Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP) & Director General, Department for the Development of Thai Traditional and Alternative Medicines, Thailand*
- 9:20 – 9:35 **Keynote Address: The Role of Health Stakeholders towards Developing Transparency and Accountability in Health Research**  
*Samlee Plianbanchang, Regional Director, World Health Organization Southeast Asia Regional Office*
- 9:35 – 9:50 **Professionalism as Key Issue the Conduct of Health Research**  
*Greg Koski, Chair, American Society of Health Reserch Professionals*
- 9:50 – 10:10 Tea and Coffee Break
- Plenary Session 2: Encouraging Accountability and Transparency in Health Research: A Muti-Stakeholder Perspective**
- Chairpersons: Dr. Vasantha Muthuswamy, *Senior Deputy Director General, Indian Council for Medical Research and FERCAP Secretary*
- 10:10–12:30 **Panel Discussion: Perspectives in Ensuring Accountability in Clinical Trials and Health Research**
- 10:10 - 10:25 **An Industry Perspective**  
*Allan Johansen, Head, Pharma Development Quality, Roche*
- 10:25 - 10:40 **Funding Agency Perspective**  
*Robert Ridley, WHO TDR*
- 10:40 – 10:55 **International Organization Perspective**  
*Tikki Pang, WHO Geneva*
- 10:55 – 11:10 **Investigator Perspective** Dr.
- Khanchit Limpakarnjanarat*
- 11:10 – 11:25 **Ethics Committee Perspective**  
*Kerry Breen*

- 11:25 - 11:40 **Regulatory Perspective**  
Vasantha Musthuswamy
- 11:40 - 11:55 **Patient/ Community Perspective**  
Beatrice Loff
- 11:55 - 12:30 Open Forum
- 12:30-13:30 Lunch Break

**Parallel Session 1: Group Discussion: Addressing Problematic Issues in  
Accountability and Transparency of Stakeholders in Health  
Research**

Chairpersons: Suriadi Gunawan, *FERCAP Steering Committee Member*  
Ock-joo Kim, *FERCAP Steering Committee Member*

- 13:30-14:30 **Group Discussions**
- Group 1 – Sponsor Responsibility**  
Chair: Detlef Niese, Novartis
- Group 2 – Investigator Responsibility**  
Chair – Kenji Hirayana, FERCAP
- Group 3 – Ethics Committee Responsibility**  
Bradley Waite, WIRB
- Group 4 – International Organization Perspective**  
Tikki Pang, WHO, Geneva

- 14:30 - 15:30 **Group Reports: Identifying Stakeholder Responsibilities in Health  
Research**
- 15:30 – 15:45 Coffee Break

**Plenary Session 3: Addressing Specific Issues related to Accountability and  
Transparency in Health Research**

Chairpersons: Marita Reyes, *FERCAP Steering Committee Member*

- 15:45-16:00 **Balancing Human Subject Protection and Facilitating Research: A  
Developing Country Perspective**  
Suwit Wiboolpolprasert, *Senior Adviser, Ministry of Public Health,  
Thailand*
- 16:00 16:45 **Using ‘Respectful Methodologies’ in Research among Vulnerable  
Populations**  
Zosimo Lee, *Dean, College of Social Science and Philosophy,  
University of the Philippines*
- 16:45 – 17:00 **Addressing Conflicts of Interest Issues during Ethical Review of  
Protocols**  
David Foster, *Vice President, Western Institutional Review Board*
- 17:00 – 17:15 **Issues and Interventions to Address Scientific Misconduct**  
Sang-Goo Shin, *Professor, College of Medicine, Seoul National  
University*

17:15 – 17:30 **Ethical Issues in the Publication of Health Research**  
Barbara Sina, *Health Science Administrator, Fogarty International  
Center, US National Institutes of Health*

17:30 – 18:00 Discussion and Open Forum

### Day 2: Thursday, 30 November 2006

8:30 - 10:30 **Roundtable Discussion I: Reports from Asian & Western Pacific  
Countries / Areas**

**The Current Status of Guidelines and Ethical Review Systems:  
Towards Public Accountability in Research**

Chairperson: Anoja Fernando, Member, FERCAP Steering Committee, Sri Lanka

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

Guide Questions

- What mechanisms and interventions are used in your country to ensure public accountability in health research?
- What government and non government organizations are involved to ensure accountability and transparency in health research?
- Are there new local laws, regulations, and guidelines related to ethical review of protocols?
- Describe the ethical review structure in your country/area
- What regulatory documents or guidelines are used by ethics committees to review protocols?
- What steps should be further undertaken to improve ethical review of research?

10:30-10:50 Coffee/Tea Break

**Plenary Session 4: Working towards Public Accountability in Research: A  
Health Systems Approach**

Chairperson: Benjamin Kuo, *Secretary General, Joint Institutional Review Board of  
Taiwan and FERCAP Vice Chair*

10:50-11:10 **Integrating Research Ethics into Health Systems Research**  
Reijo Salmela, *World Health Organization, Western Pacific Region  
(WPRO)*

11:10-11:30 **Public Perception of Transparency Issues in Drug Registration**  
Sirinart Vasanvathana, *Food and Drug Administration, Ministry of  
Public Health, Thailand*

- 11:30-11:50 **The Role of Data Safety Monitoring Boards to Ensure Accountability in Research**  
Francis Crawley, GCP Alliance, Belgium
- 11:50-12:10 **Improving Public Trust in Health Research: Implementing GCP Compliant Researches**  
Juntra Karbwang, *Clinical Coordinator, WHO-TDR*
- 12:10-12:30 **The Role of Regulatory Authorities to Address Commercialization of Research**  
Bernard Schwetz, Director, OHRP
- 12:30-13:00 Discussion
- 13:00-14:00 Lunch Break

**Parallel Session 2: Addressing Transparency Issues in Various Types of Research**

Chairperson: Kenji Hirayana, *FERCAP Steering Committee Member*

- 14:00-16:00 Parallel Session A: Informed Consent Issues  
Parallel Session B: Conflicts of Interest Issues

16:00-16:20 Coffee Break

16:20-17:00 Group Reports

**Plenary Session 5: Towards Sustaining Initiatives for Public Accountability in Research**

Chairperson Gemiliano Aligue, *FERCAP Steering Committee Member*:

- 17:00-17:20 **Proposal for a Conference Position Paper on the Potential Contribution of Asian and Western Pacific Governments to National standards for Good Ethical Review Practice**  
*Cristina E. Torres, FERCAP Coordinator*  
*Renato Manaloto, Assistant Professor, Philosophy Department, University of the Philippines*

17:20-17:30 Closing Remarks  
Vichai Chokevivat, Chairman, Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP)

## **5<sup>th</sup> FERCAP General Assembly**

**Tuesday, 28 November 2006**

### **Plenary Session 1: Reviewing the Impact of FERCAP at the National, Regional and International Levels**

10:00-10:15 **FERCAP-SIDCER Partnership: Towards Global Capacity  
Building in Ethical Review**  
*Vichai Chokevivat, Chairman, Forum for Ethical Review Committees  
in Asia & the Western Pacific (FERCAP) & Director General,  
Department of Development of Thai Traditional and Alternative  
Medicines, Thailand*

10:15-11:15 **Round Table Discussion I: Building Capacity of National Forum  
towards Quality Ethical Review**

Chairpersons:

- FERCIT
- FERCI
- FIRST
- FERCAP Phil.
- FERCI
- FERCIM

11:15 -12:00 **Awarding of SIDCER Recognition to Ethics Committees  
Compliant with International and National Standards**

12:00 – 12:15 **Report of the Treasurer and Discussion of the FERCAP Accounts  
and Budget**

*Kesara Na-Bangchang, Treasurer, FERCAP Steering Committee*

12:15-12:30 **FERCAP Plans for 2007**

12:30-12:35 **Date and place of the next Assembly**

12:35-12:45 **Close of the General Assembly**

*Vichai Chokevivat, FERCAP Chair*

12:45-14:00 Lunch

14:00 Tour of Vientiane