

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



Announcing

*An International Conference on  
Health Research and Access to Medicines  
in Asia & the Western Pacific*

*December 13-14, 2004  
Chiang Mai, Thailand*

*and*

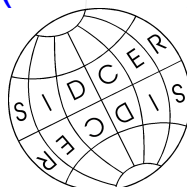
*FERCAP General Assembly*

*December 15, 2004  
Chiang Mai, Thailand*

*part of an international collaborative project organised by the*  
UNICEF/UNDP/World Bank/WHO Special Programme for Research  
and Training in Tropical Diseases (TDR)  
World Health Organization (WHO)  
World Medical Association (WMA)  
Department of Health and Human Services (DHHS), USA  
European Forum for Good Clinical Practice (EFGCP)  
International Federation of Pharmaceutical Manufacturers Associations  
(IFPMA)

*developed within the framework of the*

**Strategic Initiative for Developing Capacity in Ethical Review  
(SIDCER)**



**An International Conference on  
Health Research and Access to Medicines in Asia & the Western Pacific**  
Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP/SIDCER)  
Chiang Mai, Thailand, December 13-14, 2004  
Draft Programme, 22 August 2004, 7.0 (\*speaker to be confirmed)

**The Forum for Ethical Review Committees in Asia and Western Pacific cordially invites you to participate in this FERCAP Conference 2004 to be held in Chiang Mai, Thailand on December 13-14 and the FERCAP General Assembly to be held at the same venue on December 15, 2004.**

## Conference Description

This conference is situated within the SIDCER International Cooperative Project on Best Practices in Health Research. This project examines fundamental questions in the ethics of health research affecting resource-poor regions. SIDCER launched this project in 2003 with regional conferences in Bangkok, Thailand; Addis Abba, Ethiopia; St. Petersburg, Russia; and San José, Costa Rica. The aim of the project is to use the established partnerships within and across the SIDCER regional organizations in order to establish good ethical practices based on the development of systematic ethical review that supports ethical insight and responsibility on the part of researchers, sponsors, and government agencies. The overall aim of the project is to advance a global dialogue on Best Practices in Health Research.

The major interest of this conference is to promote the development of an Asian & Western Pacific approach for integrating health research policies with national healthcare programmes. The conference examines the development of research infrastructures in order to contribute to general health infrastructures. The aim is to develop a systematic approach to the development of medicines that maximises the availability of those medicines, in a safe and monitored environment, during and after the research.

A growing concern in research ethics, particularly with regard to the evaluation of research proposals by ethics committees, is the availability of medicines during and after research.

The project develops out of a concern to establish good ethical practices based on the development of systematic ethical review that supports ethical insight and responsibility on the part of researchers, sponsors, and government agencies. The project grows out of the international partnerships developed by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER).

This conference carries forward the work of the Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP) with regard to capacity-building for ethical review and the promotion of research subjects protections. The conference presents recent work being carried out within the FERCAP projects. It follows most directly on the FERCAP International Conference on Ethical Review in Asia & the Western Pacific: Advancing the Region's Capacity for Health Research, held on 15-16 December 2003 in Bangkok, Thailand, as well as the International Conference on Good Health Research Practices in Asia & the Western Pacific, held on 25-27 July 2002 in Chiang Mai, Thailand, and the International Conference on Ethical Issues in Health Research, held on 22-25 October 2001 at the University of the Philippines. The Conference also brings together the work of several in-country workshops held in Japan, Taiwan-China, the Philippines, Thailand, Laos, Cambodia, Vietnam, India, Indonesia, Myanmar, Korea, China, and Nepal.

The current discussion on the responsible development of research projects and the care required for research participants and their communities' forms a general framework for the conference. The conference explores current international guidelines for ethics and Good Clinical Practice, and their effect on national legislation, guidelines and research procedures.



## Conference Objectives

The primary objective of the conference is to promote the availability of medicines in Asia & the Western Pacific, focusing on developing an ethical framework for research that ensures the best treatment for participants and their communities, during and following research. Within this general framework, the following specific objectives are pursued:

- An examination of the background to decisions on trial designs and medicines availability in Asian & the Western Pacific research settings;
- An examination of the rational use of medicines in research vs. the medical and ethical requirements to prevent or treat diseases;
- The costs of medicines in research and the investment in healthcare;
- The responsibilities and limitations of ethics committees in the decisions on healthcare and medicines use in research;
- Access to medicines by research participants and their communities following research;
- The compassionate use of medicines following research;
- The relationship between medicinal development in clinical trials and the availability of medicines in regional and national healthcare;
- The responsibility of researchers and their organizations for the availability of medicinal products during and after the research;
- The development of an Asian & the Western Pacific approach to access to medicines in research settings and daily healthcare.

## Conference Outcomes

The conference will aim to achieve outcomes for further actions in the following areas:

- The contribution to an international resolution on the availability of medicines;
- The contribution to a report on current practices in Asia & the Western Pacific regarding the availability of medicines during and after research;
- An analysis of the strengths and weaknesses of current research policies in Asia & the Western Pacific and their affects on the availability of medicines;
- An analysis of the relationship between research practices and the availability of medicines in Asia & the Western Pacific;
- The development of a systematic approach in Asia & the Western Pacific to addressing the availability of medicines during and after research.

## Conference Format

A two-day conference consisting of discussion in plenary sessions and workshop groups, with a focus on the access to medicines during and after research, particularly regarding the role of Asian & the Western Pacific ethics committees.

## Conference Participants

The conference participants are Asian & the Western Pacific researchers and ethics committee members as well as international guests from leading research institutions involved in research projects in Asia & the Western Pacific.



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## Conference Language

The language of the conference is English.

## Organising Committee

Vichai Chokevivat, Chairperson, FERCAP (Thailand)

Benjamin Kuo, FERCAP (Taiwan-China)

Vasantha Muthuswamy, Secretary and Member, FERCAP (India)

Kesara Na-Bangchang, Treasurer and Member, FERCAP (Thailand)

Suraidi Gunawan, Member, FERCAP (Indonesia)

Kenji Hirayama, Member, FERCAP (Japan)

Melody Lin, OHRP DHHS (USA)

Juntra Karbwang-Laothavorn, Honorary Member, FERCAP (Switzerland)

Francis P. Crawley, Honorary Member, FERCAP (Belgium)



## FERCAP Conference Agenda

### Day 1: Monday, 13 December 2004

- 9:00-9:15 Welcoming Addresses  
**Vichai Chokevivat**, *Chairman, Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP) & Secretary General, Department of Development of Thai Traditional and Alternative Medicines, Thailand*  
Representative to Thailand, *World Health Organization*  
**Samlee Plianbangchang**, *Southeast Asia Regional Director, WHO*  
**\*James Appleyard**, *President, World Medical Association*  
**Sudarat Keyuraphan**, *Minister of Health, Thailand*

#### Opening Address

#### Global Health: Sharing the Burden

**Secretary Tommy G. Thompson**

*Secretary of Health and Human Services  
Department of Health & Human Services (DHHS)  
USA*

#### Plenary Session 1: The Responsibility of Society to Ensure Access to Medicines

- Chairpersons: **Vasantha Muthuswamy**, *Forum for Ethical Review Committees in India (FERCI)*  
**\*William Steiger**, *Director of the Office of Global Health Affairs and Special Assistant to the Secretary for International Affairs, Department of Health & Human Services (DHHS), USA*
- 9:15-9:45 Keynote Address: Equity and Responsibilities in Providing Access to Medicines: The Roles of Physicians, Researchers, Manufacturers, and Governments  
**Samlee Plianbangchang**, *Southeast Asia Regional Director, World Health Organization*
- 9:45-10:05 The Responsibility of the Physician to the Patient, and the Responsibility of Society to the Physician  
**\*Delon Human**, *Secretary General, World Medical Association (WMA)*
- 10:05-10:30 The Role of the Manufacturing Industry in Providing Medicines to Patients and Their Health Providers: Exploring Cross-Sectorial Possibilities  
**Harvey E. Bale**, *Director General, International Federation of Pharmaceutical Manufacturers Associations (IFPMA)*
- 10:30-11:00 Coffee/ Tea Break



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- 11:00-12:30 Working Groups, Session I: Establishing Principles for Access to Medicines in Asia & the Western Pacific  
Introduction: *\*Speaker invited*
- What are the needs for access to medicines in Asia & the Western Pacific?
  - What are the challenges to access to medicines in Asia & the Western Pacific?
  - Who is responsible and capable of ensuring access to medicines?
  - What ethical, economic, and political principles should guide discussions on access to medicines?
- 12:30-14:00 Lunch
- Plenary Session 2: Examining the Role of Ethics Committees in Regarding Access to Medicines before and after Research**
- Chairpersons: *\*Yoshikazu Hayashi, Deputy Director, Evaluation and Licensing Division, Pharmaceutical & Food Safety Bureau, Ministry of Health, Labour and Welfare, Japan*  
*Nirmal Kumar Ganguly, Director General, Indian Council for Medical Research (ICMR)*
- 14:00-14:50 Reports from Session I of the Working Groups and Plenary Discussion
- 14:50-15:10 The Role of Ethical Review in Ensuring Appropriate Medical Care for Research Participants  
*Benjamin Kuo, Joint IRB & Laboratory of Epidemiology and Biostatistics, Department of Medical Research and Education, Veterans General Hospital-Taipei, Taiwan-China*
- 15:10-15:30 The Impact of Ethical Review Procedures and National Review Systems on Access to Medicines  
*Gemiliano D Aligui, Education Officer, FERCAP*
- 15:30-16:00 Coffee Break
- 16:00-16:20 Developing Continuity between Health Research and Health Care: Responsibilities to Research Participants and Their Communities  
*Mary Ann Lansang, Executive Director, International Clinical Epidemiology Network (InCLEN), The Philippines*
- 16:20-16:40 Negotiating with Ethics Committees and Negotiating with National Authorities: What is Possible during Research & What is Possible after the research?  
*Marc Lallemand, Programme for HIV Prevention & Treatment, Chiang Mai, Thailand*



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16:40-17:30 **Roundtable Discussion I: The Medicines Market Place and Ethics in Asian & Western Pacific Clinical Research: The Role of Ethics Committees in Ensuring Access to Medicines**

Moderator: \**Angela Bowen, President, Western Institutional Review Board (WIRB), Olympia, Washington, USA*

Panelists:

\**Melody H. Lin, Deputy Director, Office for Human Research Protections, Department of Health & Human Services (DHHS), USA*

*Gopal P. Acharya, Chairman, Nepal Health Research Council, Kathmandu, Nepal*

*Vasantha Muthuswamy, Forum for Ethical Review Committees in India (FERCI)*

- What are the current expectations of clinical trial participants regarding access to medicines in Asia & the Western Pacific?
- What are the expectations of researchers and manufacturers from the market place and governments?
- What models for cooperation can be envisaged to improve research participant and patient access to medicines?

## **Day 2: Tuesday, 14 December 2004**

**Plenary Session 3: Addressing Ethical Issues in Health Research in Asia & the Western Pacific**

Chairpersons *H.M. Sambas Wiradisuria, National Commission on Health Research Ethics & Professor of Child Health, Department of Child Health, School of Medicine, Universitas Padjadjaran, Indonesia*

\**Bernard Schwetz, Director, Office for Human Research Protections, Department of Health & Human Services (DHHS), USA*

8:30-11:00 **Round Table Discussion II: Reports from Asian & Western Pacific Countries on Current Developments in Ethical Review Procedures and Cooperation**

Panelists: Representatives from Cambodia, Chinese Taipei, India, Indonesia, Japan, Korea, Laos, Malaysia, Mongolia, Nepal, Peoples Republic of China, Philippines, Samoa, Singapore, Sri Lanka, Taiwan-China, Thailand, Vietnam

- What are the major developments in ethical review procedures in each country over the past year?
- What are the major challenges ethics committees are currently encountering in each country?
- What organizations exist to support ethical review in each country? Is there a FERCAP national forum; and, if so, how does it function?
- What are the current guidances available for ethical review in each country?
- What is the current status of the use of the WHO *Operational Guidelines for Ethics Committees That Review Biomedical Research* and the companion guideline *Surveying and Evaluating Ethical Review Practices*?
- Is there a national system for ethical review in each country? If not, is this being developed?
- What steps are foreseen to improve ethical review in each country?



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- 11:00-11:30 Coffee / tea break
- 11:30-13:00 Working Groups, Session II: The Development of Ethical Review Practices and the Rise of Ethical Issues in Health Research  
Introduction: *Alex Capron, Director, Ethics, Trade, Human Rights and Health Law, World Health Organization (WHO)*
- Which ethical issues currently pose the largest challenge to health research in Asia & the Western Pacific?
  - What is the role of ethics committees in addressing ethical issues? nationally, in Asia, globally?
  - Which developments in ethical review practices are needed to address the current ethical issues and advance health research?
  - What role should ethics committees play in developing access to medicines?

13:00-14:00 Lunch

**Plenary Session 4: Ethics on the Frontiers of Health Research in Asia & the Western Pacific**

Chairpersons: \*Jie Chen, Professor, School of Public Health, Fudan University, Shanghai, China  
Rob Ridley, *Acting Director, UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR), WHO*

14:00-15:00 Reports from Session II of the Working Groups and Plenary Discussion

15:00-15:20 Managing Clinical Trials and Drug Registration with a View toward Patient & Community Access to Medicines: The Costs of Medicinal Development & the Investment in Healthcare  
*\*Herng-der Chern, Deputy Executive Director, Center for Drug Evaluation, Taiwan-China & Network of Pharmaceutical Regulatory Science, Asia-Pacific Economic Cooperation (APEC)*

15:20-15:40 Developing Medicines to Meet the Access Needs of Disease-Endemic Countries: Investment, Profit, & Health Decisions  
*\*Yves Juillet, Global Cooperation Group & Steering Committee, International Conference on Harmonization (ICH); Chairman, Asian Regulatory Committee (IFPMA); & Senior Advisor, Les Entreprises du Médicament (LEEM), France*

15:40-16:00 Coffee and Tea

16:00-16:20 Discovering, Developing, and Providing Medicines across the Public-Private Demarcation Line: Sharing Responsibilities for Health Care across Boundaries  
*\*Raymond V. Gilmartin, Chairman, President and CEO, Merck & Co., Inc.*

16:20-16:40 Developing an Asian Awareness and a Global Vision on Access to Medicines: Creative Strategies to Address the 10/90 Divide  
*Suwit Wiboonpolprasert, Deputy Permanent Secretary, Ministry of Health, Thailand*





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16:40-17:10 **Roundtable Discussion III: An Asian Contribution to a Resolution on Access to Medicines**

Moderator: Vichai Chokevivat, *Chairman, Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP) & Secretary General, Department of Development of Thai Traditional and Alternative Medicines, Thailand*

Panelists:

\*Speaker invited

Anoja Fernando, *Member of the FERCAP Steering Committee, Sri Lanka*

\*Jie Chen, Professor, School of Public Health, Fudan University, Shanghai, China

- How can we summarise our discussions in a Resolution on Access to Medicines?
- How can we continue the discussion with FERCAP's SIDCER partners and the WHO & WMA on the Resolution on Access to Medicines?
- What role should ethics committees have in Asian & Western Pacific societies?

17:10-17:15 Close of the Conference

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



# **The 4<sup>rd</sup> FERCAP General Assembly**

## **Chiangmai, Thailand**

**Wednesday, 15 December 2004**

The FERCAP General Assembly meets at least once every two years with the aim of bringing together the members of FERCAP in order to evaluate the objectives, challenges, achievements, and future plans of the organisation.

The First General Assembly was held in Bangkok on 12 January 2000 and marked the founding of FERCAP; the Terms of Reference were decided upon and first activities were planned. During the Second General Assembly in 31 July 2002 in Bangkok, the activities of the previous two years were reviewed, a strategic plan adopted, and the Terms of Reference amended. The third FERCAP General Assembly was held on 17 December 2003 in Bangkok, Thailand, focusing on the review of the organizational structure of FERCAP, the 3 year strategic plan, and the growth of national, regional, and international cooperation.

This Fourth General Assembly focuses on consolidating the achievements of FERCAP over the past four years, and reviews its strategic development according to the outcomes of the FERCAP International Conferences on ‘Good Health Research Practices in Asia & the Western Pacific’ (25-27 July 2002, Chiang Mai, Thailand) and ‘Ethical Review in Asia & the Western Pacific: Advancing the Region’s Capacity for Health Research’ (15-16 December 2003, Bangkok, Thailand) as well as the International Conference - ‘Health Research and Access to Medicines in Asia & the Western Pacific’ (29-30 November 2004, Bangkok, Thailand). The focus of this General Assembly is on the impact of the work of FERCAP on health research – at the national, regional, international levels – over the past five years and its contribution to the development of ethical review in Asia and the Western Pacific.

## Agenda for the FERCAP 2004 General Assembly

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

Chairpersons: Suraidi Gunawan, Member, FERCAP Steering Committee  
Vasantha Muthuswamy, Secretary, FERCAP Steering Committee

- 8:30-9:00 The FERCAP Vision: Revisited and Regained  
*Vichai Chokevivat, Chairman, Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP) & Secretary General, Department of Development of Thai Traditional and Alternative Medicines, Thailand*
- 9:00-9:20 The Work of the National Fora for Ethical Review within the FERCAP Region: An Impact Analysis  
*Vasantha Muthuswamy, India (FERCI)*  
§ *Thailand (FERCIT)*  
§ *Nepal (FERCIN)*  
§ *Philippines*  
§ *India*  
§ *Japan*  
§ *Korea (KAIRB)*
- 9:20-9:40 The Development of Performance Assessment & Accreditation Models for Ethical Review in Asia & the Western Pacific  
*Sopit Thamaree, Secretary, Forum for Ethical Review Committees in Thailand (FERCIT)*
- 9:40-10:00 The Impact of Training Courses & Fellowship Programmes on Ethics Committees in the FERCAP Region: A Critical Evaluation  
*Kenji Hirayama, Member, FERCAP Steering Committee*
- 10:00-10:30 **Roundtable Discussion 1: What is the face of FERCAP? and what is the character of FERCAP?**
- 10:30-11:00 Coffee / tea break
- 11:00-12:30** Working Groups Session: Review of the WHO/TDR Guideline for establishing and functioning of a DSMB
- 12:30-14:00 Lunch



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**Plenary Session 2: The Road Ahead for FERCAP**

- Chairpersons: Leonardo D. de Castro, Vice-Chairperson, FERCAP  
Mahani Mansor, Member, FERCAP Steering Committee
- 14:00-14:45 Reports from the Working Groups and Plenary Discussion
- 14:45-15:15 Presentation of the FERCAP Strategic Plan for 2005-2007  
*Vichai Chokevivat, Chairman, Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP)*
- 15:15-16:15 **Roundtable Discussion: Critical Evaluation of the FERCAP Strategic Plan: Is FERCAP having the impact it desires? What are our strengths? our weaknesses? How can we shape our impact to be more effective?**
- 16:15-16:30 Report of the Treasurer and Discussion of the FERCAP Accounts and Budget  
*Kesara Na-Bangchang, Treasurer, FERCAP Steering Committee*
- 16:30-17:00 Report of the Secretary and Discussion of the Future Planned Activities for FERCAP  
*Vasantha Muthuswamy, Secretary, FERCAP Steering Committee*
- 17:00-17:20 Review of the FERCAP Terms of Reference and Steering Committee Membership  
*Vasantha Muthuswamy, Secretary, FERCAP Steering Committee*
- 17:20-17:25 Date and place of the next Assembly  
*Vasantha Muthuswamy, Secretary, FERCAP Steering Committee*
- 1725-1730 Close of the General Assembly  
*Vichai Chokevivat, Chairman, Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP)*

