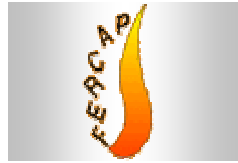


Forum for Ethical Review Committees in Asia & the Western Pacific



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

Announcing

*An International Conference on
Ethical Review in Asia & the Western Pacific*
**ADVANCING THE REGION'S CAPACITY
FOR HEALTH RESEARCH**

15 - 16 December 2003



Bangkok, Thailand

Ethical Review in Asia & the Western Pacific
Advancing the Region's Capacity for Health Research
Bangkok, Thailand
15-17 December 2003

The Forum for Ethical Review Committees in Asian and Western Pacific cordially invites you to participate in FERCAP Conference 2003 to be held at the Royal River Hotel in Bangkok, Thailand on 15-16 December 2003 and the FERCAP General Assembly to be held at the same venue on 17 December 2003.

Conference Description

This FERCAP 2003 International Conference examines the role of ethics committees in contributing to the development of health research in Asia & the Western Pacific, with a particular focus on leading ethical issues currently being addressed within the region. The Conference focuses on the central role given to ethics in decision-making on health research within the Asia & Western Pacific region, particularly the role of ethics committees in the region. The Conference brings together work performed in this area by FERCAP members along with leading experts from other regions engaged in collaborative research with partners in the Asian & Western Pacific, in particular, the international partnerships developed within the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER).

The Conference presents recent work being carried out within the FERCAP projects. It follows most directly on the FERCAP conference on the International Conference on Good Health Research Practices in Asia & the Western Pacific, held on 25-27 July 2002 in Chiang Mai, Thailand, as well as 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, the Philippines, Thailand, Laos, Cambodia, Vietnam, India, Indonesia, Myanmar, Korea, China, and Nepal.

The current discussion on the role of ethics committees in ensuring the in-country and regional development of capacity for health research forms a general framework for the Conference. The Conference examines this discussion by looking at international and national guidance on specific issues in health research and examining their value against specific cases studies that illustrate the issues.

Conference Objectives

The primary objective of the conference is to promote ethics as the cornerstone for building health research in Asia & the Western Pacific region. Within the framework of this leading objective, the following specific objectives will be pursued:

- examining the current issues facing ethics committees and health researchers in Asia & the Western Pacific;
- improving the relation between ethics committees and national regulatory authorities;
- examining the impact of Good Clinical Practice on ethical review and health research in Asia & the Western Pacific;
- critically evaluating the impact of the work of FERCAP over the past three years;
- assisting in the sharing of ethical perspectives between FERCAP and the other SIDCER member fora: PABIN, FLACEIS, FECCIS, FOCUS; and,
- examining relevant case studies and guidance documents impacting on current ethical issues in Asia & the Western Pacific.



Conference Outcomes

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

- A report on the contribution of FERCAP to the development of ethical review in Asia & the Western Pacific, including a critical evaluation of the approach taken by FERCAP since its founding in January 2000;
- An analysis of the strengths and weaknesses of international & national guidances regarding specific ethical issues now being addressed in the context of health research in Asia & the Western Pacific;
- The identification of a FERCAP approach to promoting ethics in health research through capacity-building in ethical review; The development of a FERCAP strategic paper on building capacity in ethical review for advancing capacity in health research within the region.

Conference Format

A two-day conference consisting of discussion in plenary sessions and working groups, with a focus on an examination of guidance documents and case studies concerning specific ethical issues central to the advancement of health research Asia and the Western Pacific. The following themes are treated:

- The Role of Ethics in Health Research in Asia & the Western Pacific
- Placing Ethics at the Centre of Medicinal Development
- Addressing Ethical Issues in Health Research in Asia & the Western Pacific
- Ethics on the Frontiers of Health Research in Asia & the Western Pacific

Conference Participants

The participants are FERCAP members; Asian & Western Pacific researchers, research organisations, regulatory authorities; and invited international experts.

Conference Language

The language of the conference is English.

Organising Committee

Vichai Chokevivat, Chairperson, FERCAP (Thailand)
Leonardo D de Castro, Vice-Chairperson, FERCAP (Philippines)
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)
Juntra Karbwang-Laothavorn, Honorary Member, FERCAP (Switzerland)
Francis P. Crawley, Honorary Member, FERCAP (Belgium)



FERCAP Conference Agenda

Day 1: Monday, 15 December 2003

Plenary Session 1: The Role of Ethics in Health Research in Asia & the Western Pacific

Chairpersons: Jia-Qi Xu, Director, Department of Drug Safety and Inspections, State Drug Administration (SDA), People's Republic of China
Vasantha Muthuswamy, Forum for Ethical Review Committees in India (FERCI)

9:00-9:15 Opening 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*
Permanent Secretary, *Ministry of Public Health, Thailand*
Juntra Karbwang, *Special Programme for Research and Training in Tropical Diseases (TDR), World Health Organization*

9:15-9:45 Keynote Address: The Importance of Research Ethics to the Development of Healthcare in Asia & the Western Pacific

Deputy Minister of Health, Thailand

9:45-10:05 Ethics As a Bridge between Research and Practice in National Healthcare
Hidefumi Nakamura, Director, Division of Clinical Research, National Center for Child Health and Development, Japan

10:05-10:30 The Insistence on Ethics and the Achievement of Health: Asian Values in Dialogue with Western Medicine
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

10:30-11:00 Coffee/ Tea Break

11:00-12:30 Working Groups, Session I: Examining the Role of Ethics in Health Research

Introduction: *Guenther Forster (Medical Director China, Roche Pharmaceuticals)*

- What contribution does ethics make to health research?
- Whose values? Whose ethics? What ethical choices are open to Asians in health research?
- Who is responsible for ethical decision-making in health research?
- What priority should be given to ethics in health research?

12:30-14:00 Lunch



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Plenary Session 2: Placing Ethics at the Centre of Medicinal Development

Chairpersons: Leonardo de Castro, *Vice Chair, Forum for Ethical Review*
Kenji Hirayama, *Nagasaki University & Forum for Ethics Committees in Japan*

- 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 the Globalisation of Good Clinical Practice
Francis P. Crawley, Secretary General & Ethics Officer, European Forum for Good Clinical Practice (EFGCP)
- 15:10-15:30 The Development of Ethics among Regulatory Authorities in Asia & the Western Pacific
Nirmal Kumar Ganguly, Director General, Indian Council for Medical Research (ICMR)
- 15:30-16:00 Coffee Break
- 16:00-16:20 Assuring Patient Confidentiality and Data Protection in Clinical Research
Benjamin Kuo, Joint IRB & Laboratory of Epidemiology and Biostatistics, Department of Medical Research and Education, Veterans General Hospital-Taipei, Taiwan
- 16:20-16:40 Defining the Role of Ethics Committees vis-à-vis Regulatory Authorities in the Protection of Human Subjects
John C.W. Lim, Director, Centre for Pharmaceutical Administration & Acting Director, Centre for Drug Evaluation, Singapore
- 16:40-17:30 **Roundtable Discussion I: Ethics and the Asian & Western Pacific Clinical Research Market Place: The Role of Ethics Committees in the Development of Medicines**
Moderator: *Juntra Karbwang, Product Development, Special Programme for Research and Training in Tropical Diseases (TDR), World Health Organization*
- What are the expectations for ethical review in Asia & the Western Pacific? Are there concerns specific to this region?
 - Are ethics committees a barrier to research? Should ethics committees promote research?
 - In what ways are the developments of ethical review in Asia & the Western Pacific similar to the development of the region's research market? In what ways are ethics committees part of that market? different from that market?



Day 2: Tuesday, 16 December 2003

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*
Sirinart Vasanavathana, *Office Manager, Forum for Ethical Review in Asia & the Western Pacific (FERCAP) & Division of Drug Control, Food & Drug Administration, Thailand*

8:30-10:30 Round Table Discussion II: Reports from Asian & Western Pacific Countries on Current Ethical Issues That Challenge Ethical Review

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

- What are the major developments in ethical review 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*?
- What steps are foreseen to improve ethical review in each country?

10:30-11:00 Coffee / tea break

11:00-12:30 Working Groups, Session II: The Development of Ethical Review Practices and the Rise of Ethical Issues in Health Research

Introduction: *Francis P. Crawley, Secretary General & Ethics Officer, European Forum for Good Clinical Practice (EFGCP)*

- 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?
- Which developments in ethical review practices are needed to address the current ethical issues and advance health research?

12:30-14:00 Lunch



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

Chairpersons: Kenji Hirayama, *Forum for Ethical Review Committees in Japan*
Alex Capron, *Director, Bioethics, WHO, Switzerland*

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

15:00-15:20 Ethical, Legal, and Social Implications of Research on the Human Genome and Stem Cells in Korea
Kuchan Kimm, Investigator-in-Chief & Acting Director, National Genome Research Institute, Korea

15:20-15:40 The Use of Genetic Material and Genetic Data in Health Research: Researchers, Communities, and Publishers Confronting Ethics
Partha Majumder, Anthropology and Human Genetics Unit, Indian Statistical Institute, Kolkata, India

15:40-16:00 Coffee and Tea

16:00-16:20 Ethical Issues in the Use of Genetics in Drug Discovery and Development: Genomics in an Asian and Global Research Setting
Klaus Lindpaintner, Vice-President of Research and Head, Roche Genetics and Roche Center for Medical Genomics, Switzerland & European Association for Bioindustries (EuropaBio)

16:20-16:40 Protecting Genetic Resources in Developing Countries: The Impact on Health Research in China'
Gwendolyn Zahner, Visiting Professor, Beijing Genomics Institute, Chinese Academy of Sciences, Peoples Republic of China

16:40-17:10 **Roundtable Discussion III: The Asian Researcher: Partnerships in Ethics & Science**

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*

- What partnerships exist in the Asian & Western Pacific region for fostering research and protecting research participants?
- Is a partnership between ethics committees and researchers needed? desirable? Between ethics committees and regulatory authorities? Between ethics committees and sponsors?
- 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) & Secretary General, Department of Development of Thai Traditional and Alternative Medicines, Thailand



The 3rd FERCAP General Assembly

Bangkok, Thailand

Wednesday, 17 December 2003

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.

This Third 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 conference - '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). The impact of the work of FERCAP over the past four years and its contribution to the development of ethical review in Asia and the Western Pacific are the focus of this General Assembly.

Agenda for the FERCAP 2003 General Assembly

Plenary Session 1: The Achievements of FERCAP Since January 2000

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

- 8:30-9:00 The Role of FERCAP in the Advancement of Health in Asia & the Western Pacific: The First Three Years
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 Establishment of National Fora for Ethical Review within the FERCAP Region: Presence, Role, & Development
Vasantha Muthuswamy, India (FERCI)
- *Thailand (FERCIT)*
 - *Nepal (FERCIN)*



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- *Philippines*
 - *Japan*
 - *Korea (KAIRB)*
- 9:20-9:40 The Development of Performance Assessment & Accreditation Models for Ethical Review in Asia & the Western Pacific
Sopit, Secretary, Forum for Ethical Review Committees in Thailand (FERCIT)
- 9:40-10:00 The Development of Training Courses & Fellowship Programmes for Members of Ethical Review Committees in Asia & the Western Pacific
Kenji Hirayama, Member, FERCAP Steering Committee
- 10:00-10:30 **Roundtable Discussion 1: Self-Evaluation of the First Three-year Development of FERCAP**
- 10:30-11:00 Coffee / tea break
- 11:00-12:30 **Working Groups Session: Review of the Draft WHO/TDR Standard Operating Procedures for Data and Safety Monitoring Boards**
- 12:30-14:00 Lunch

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 2004-2006
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: Will the Achievement of FERCAP Goals Advance Health in Asia & the Western Pacific**
- 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
- 17:00-17:25 Review of the FERCAP Terms of Reference and Steering Committee Membership
Vasantha Muthuswamy, Secretary, FERCAP Steering Committee
- 17:25-17:30 Close of the General Assembly
Vichai Chokevivat, Chairman, Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP)

