

An International Conference on
Developing Quality Systems in Health Research:
Towards Better Human Subject Protection

Udon Thani, Thailand*
Charoensri Grand Hotel

November 28-29, 2007
FERCAP General Assembly – 30 November 2007



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)

WHO SEARO & WPRO

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

Introduction

International guidelines and national laws have been formulated to protect human subjects in research. But their implementation is dependent on the willingness of various stakeholders to uphold the highest ethical standards in the implementation of health research. The implementation of the highest standards can best be maintained through the creation of effective quality systems in the various stages of the research process. This conference will examine various models, good practices and initiatives to ensure quality systems in the conduct of health research. Quality systems contribute to credible data and the protection of the rights and safety of human subjects in research. Ensuring quality data begins from protocol development and approval, to ethical research implementation, monitoring and data management, until completion of final report. Defining the roles and contribution of various research stakeholders to quality systems constitute the first step towards quality improvement. Training and certification programs for investigators and ethics committee members can ensure qualified persons performing their functions. Through plenary and parallel sessions, group discussions and country reports, the full range of quality systems and their contribution to human subject protection will be explored.

Objectives

General objective:

To identify and explain various models of quality systems in health research that contribute to human subject protection

Specific objectives:

- To describe the roles, responsibilities and contribution of various research stakeholders to ensure quality in various stages of the research process
- To describe current models and practices of regulatory systems that may be replicated in various country settings
- To describe current interventions that contribute to capacity building of research stakeholders including investigators and ethics committee members
- To describe current quality systems that are in place in countries in the Asia Pacific
- To identify gaps, facilitators and barriers to quality systems in health research
- To suggest options and future direction of quality management systems to maintain the highest ethical standards in health research
- To develop relevant Asian models of ethical research infrastructure that promote quality systems 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. 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 conference should be able to contribute to better awareness and knowledge about the link between quality systems and better human subject protection to develop better quality procedures in health research.

FERCAP 2007 Conference Agenda

Day 1: 28 November 2007

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

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

Welcome Address

Hon. Dr. Mongkol Na Songkhla, *Thailand Health Minister*

Welcome Remarks

Luecha Wanaratana, Director General, Department for Development of Thai Traditional and Alternative Medicine, MOPH, Thailand

Introduction of Guests/ Delegation

Vichai Chokevivat, Chairman, Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP) and Institute for Development of Human Research Protection (IHRP)

9:30 – 10:30 **Plenary Session 1: Developing a Quality System Framework in Health Research**

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

Linking the Stakeholders: Towards Developing a National Quality System in Health Research

Marita Reyes, Philippine Health Research Ethics Board Chair, FERCAP Steering Committee Member

International Clinical Research Coordination Center: Towards Excellence in Clinical Research

Kitima Yuthavong, Thailand Center for Excellence in Life Sciences

Improving Quality of Ethical Review: Reinforcing Good Practices during SIDCER Surveys

Cristina E. Torres, FERCAP Coordinator

Open Forum

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

**11:00 - 12:30 Plenary Session 2: Encouraging Quality Systems in Health Research:
Some Regulatory Models/ Concepts**

Chairpersons: Ock-joo Kim, FERCAP Steering Committee Member

The European Inspection System

Gunnar Danielsson, EMEA Sweden

**Implementing Indian Guidelines and Regulations for Human
Subject Protection**

*Vasantha Musthuswamy, Senior Deputy Director General,
Indian Council for Medical Research and FERCAP Secretary*

Improving Quality of IRBs through Regulatory Audit

Hsueh Jui-Yuan, Bureau of Medical Affairs Director, Taipei

Regulatory Oversight over Stakeholder Roles and Responsibilities

*Renato Manaloto, Assistant Professor, University of the Philippines,
Diliman*

Open Forum

12:30 -13:30 Lunch Break

13:30 – 15:30 Plenary Session 3: Developing a Quality System in Ethical Review

Chairpersons: Benjamin Kuo, FERCAP Vice Chair
Dr. Tada Sueblivong, FERCIT Chair

**Establishing Joint Institutional Review Boards: Benefits and
Concerns**

Low - Tone Ho, Joint Institutional Review Board, Taipei

**Institutional Initiatives towards National Capacity Building in
Ethical Review**

*Vicente Belizario, Deputy Director, Philippine National Institutes of
Health*

Efficiency Issues in Institutional Review Board Management

*Ock-joo Kim, Korean Association of Institutional Review Boards &
FERCAP Steering Committee Member*

**Developing Good Practices in IRB Monitoring of Research
Implementation**

Bradley Waite, Western Institutional Review Board

Open Forum

15:30 - 16:00 Coffee Break

16:00 – 17:30 Plenary Session 3: Capacity Building for Strengthening of Ethical Culture in Health Research

Chairperson: Dr. Reijo Salmela, World Health Organization, Western Pacific Regional Office

Investigator Certification

Greg Koski, Chair, American Society of Health Research Professionals

Sensitizing Investigators in Ethical Issues in Research

Amar Jesani, Centre for Studies in Ethics and Rights, Indian Journal of Medical Ethics

Addressing Social and Cultural Issues in Health Research

Anant Bhan, Gates Ethical, Social and Cultural Framework Project

Training and Casebook on Ethical Issues in International Health Research

Abha Saxena, World Health Organization, Geneva

Open Forum

18:30 Welcome Dinner

Day 2: Thursday, 29 November 2007

8:00 - 10:00 Roundtable Discussion: The Current Status of Quality Systems in Health Research: Reports from the FERCAP Regional Network

Chairperson: Anoja Fernando, FERCAP Steering Committee
Aneck Aribarg, Thai Joint Research Ethics Committee Chair

Guide Questions

- What initiatives have been undertaken to ensure quality systems in health research? How are GCP principles implemented in your area?
- How do public agencies/ government organizations ensure quality health research?
- Describe some sound ethical review structures and practices of ethics committees to ensure quality research.
- Identify some facilitating factors, barriers and gaps to quality systems in ethical review?
- Is there a national registry of clinical trials? Describe how it works and how it contributes to quality research.

10:00 -10:30 Coffee/Tea Break

10:30 – 12:30 Plenary Session 4: Implementing Safeguards for Quality Research

Chairperson: Sopit Thamaree, Joint Research Ethics Committee, Thailand
Kenji Hirayana, Dean, Nagasaki Institute for Tropical Medicine

Impact of SIDCER Recognition on Quality of Traditional Chinese Medicine Research

Xiong Ningning, Affiliated Hospital of Nanjing University for TCM

Designing Ethically Sound Protocols

Edmund Tsuei, Roche Products Pty Limited

Media as Vanguard for Human Subject Protection

Young Mo Koo, Asan Medical Center

Ethical Consideration for Phase I Studies

Dr. Teh-Min, National Defense Medical Center. Taipei

Legal Institutional Responsibility in Clinical Trials: A Malaysian Framework

Kulenthran Arumugam, National Ethics Committee of Malaysia

Open Forum

12:30-13:30 Lunch Break

13:30 – 15:30 Participatory Session: Fostering Good Practice and Quality Ethical Systems in Health Research

Chairperson: Marita Reyes, FERCAP Steering Committee
Suriadi Gunawan, FERCAP Steering Committee

15:30-16:00 Coffee Break

16:00- 17:00 Summary of Conference Discussions – Panel Chairs

17:00 – 17:15 Closing Ceremonies
Vichai Chokevivat, FERCAP Chair

7th FERCAP General Assembly

30 November 2007

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

- 8:00 – 8:15 **FERCAP-SIDCER Partnership: Towards Global Capacity Building in Ethical Review**
Vichai Chokevivat, Chairman, Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP)
- 8:15 – 9:00 **Action Planning: Developing National Systems for Quality and Ethically Sound Research**
FERCAP Members and National Forum Representatives
- 9:00 – 11:00 **Awarding of SIDCER Recognition to Ethics Committees Compliant with International and National Standards**
- 11:00 – 11:30 **FERCAP Membership and Organizational Matters**
- 11:30 – 11:45 **Report of the FERCAP Treasurer**
Kesara Na-Bangchang, Treasurer, FERCAP Steering Committee
- 11:45 -12:00 **Close of the General Assembly**
Vichai Chokevivat, FERCAP Chair

Other Activities

Activity	Time	Venue
Practical Training for Protocol Review for Recognized and Surveyed IRBs	November 27 13:00 - 17:00	Charoensri Grand Hotel
AREC Meeting (Forum for recognized IRBs)	November 30 14:00 – 16:00	Charoensri Grand Hotel
Lao Trip	December 1	7:30 am – 6pm
SIDCER Surveyors' Training	December 2 13:00 - 16:00	Richmond Hotel Bangkok

***Travel:**

Udon thani is located in the northeastern part of Thailand, near the Mekong River, along the Thai-Lao border. Additional travel visa for those who wish to visit Vientiane, Laos may be obtained at the border.

International Travel:

International flight to Bangkok

Domestic Travel

- Domestic flight to Udon Thani (via Nok Air, Thai Air Asia or Thai Airways)
- Train or bus

Conference Fee:

FERCAP Members: US\$150.00 (with lunch and 2 snacks)

Non Member: US\$200.00 (with lunch and 2 snacks)

Contact Person:

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