An International Conference on
Defining the Roles, Responsibilities, and Relations between National Health Authorities and Ethics Committees in Health Research

Pattaya, Thailand
12-13 December 2005

Forum for Ethical Review Committees
in Asia & the Western Pacific
FERCAP/SIDCER

FERCAP General Assembly – 14 December 2005

Introduction

Abuses in the conduct of clinical trials have resulted in public indignation leading to increased regulation of health research. This development marked the advent of state interest and intervention in biomedical research for the protection of human subjects. Henceforth, national health authorities have assumed important functions and have become important actors in the field of bioethics.

This conference will examine the various paradigms to define the roles and responsibilities of national health authorities in health research, particularly their relationship with ethics committees. Through plenary and parallel sessions, group discussions and country reports, the full range of government involvement is explored, from its conceptual underpinning to its role in day-to-day regulation and the development of national systems of ethical review.

Objectives

The primary objective of the Conference is to examine the roles, responsibilities, and relations of National Health Authorities and ethics committees in Asia & the Western Pacific 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 objectives:

- to describe and compare the roles of and responsibilities of national health authorities related to the creation of an ethical infrastructure in the Asian and Western Pacific region;

- to examine the impact of current international guidelines in ethics on national legislation, guidelines, regulation, and research procedures;
- to identify and share best practices in creating effective health research systems that protect human subjects, research participants;
- to consider best practices 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 between National Health Authorities and Ethics Committees;
- to develop a relevant Asian model of ethical research infrastructure that integrates health research policies with national healthcare programs 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 support by working groups where specific issues 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 2005 Conference Agenda

Day 1: Monday, 12 December 2005

8:00 - 8:30 Registration

Plenary Session 1: Proposing a Framework for Governance, Ethics and Biomedical Research

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

8:30 - 8:45 **Conference Overview and Introduction of the Ministerial Guests**
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*

8:45 - 9:00 **Welcome Address: Establishing Research Objectives for Public Health in Asia & the Western Pacific**
Suchai Charoenratanakul, *Minister of Public Health, Thailand*

9:00 - 9:15 **Developing a National Framework for Human Subjects Protections in Health Research**
Minister for Science, India

9:15 – 9:35 **Government Support and Development for Ethical Review Committees**
Xu Jiajqi, Deputy Director General, Safety Inspection Department, State Foods and Drugs Administration (SFDA), China

8:35 – 9:50 **Good Clinical Practice Inspections and Ethical Review: Complimentatry Activities for Human Subjects Protections**
Ahwini Kumar, Drug Controller General, India

9:50 – 10:10 **Scientific Advancement, Ethics and Regulation: Developing National Regulations for Health Research**
Hon Geun-Tae Kim, Korean Minister of Health and Welfare

10:10 – 10:30 Discussion

10:30 – 11:00 Tea and Coffee Break

Plenary Session 2: Creating Ethics Infrastructure in Asia and the Western Pacific: National Legislation and Guideline Formulation and Alternative Mechanisms

Chairpersons: Anoja Fernando, Member, FERCAP Steering Committee, Sri Lanka
Thongchai Thavichachart, President, Thailand Center of Excellence for Life Sciences (TCELS)

10:20–10:40 **International Developments in Good Clinical Practice and Ethics in Health Research: Toward Societal Responsibility in Research**
Francis P. Crawley, Secretary General, European Forum for Good Clinical Practice (EFGCP)

10:40 – 11:00 **Research, Ethics, and National Development: The Role of National Health Authorities**
Vasantha Muthuswamy, Deputy Director General of the Indian Council for Medical Research; FERCAP Secretary General

11:00 – 11:20 **Legal Implications of International Guidelines in Biomedical Research: The Role of Regulatory Authorities**
Colin Thomson. Professorial Fellow, Faculty of Law, University of Wollongong, New South Wales, Australia

11:20 - 11:40 **Industry Perspective Regarding Appropriate Mechanisms for Ethical Review**
Harvey Bale, Director General, International Federation of Pharmaceutical Manufacturers Association

11:40–12:00 **Triple Burden and Triple Opportunity: Ethics and National Governance**
Alex Capron, Director, Department of Ethics, Trade, Human Rights, and Health Law, WHO

12:00 – 12:20 **Approaches in Developing a National Ethical Infrastructure: Legislation vs. Guideline Formulation**
Leonardo de Castro, Vice-President, FERCAP

12:20-12:30 Discussion

12:30-13:30 Lunch / Viewing Poster Exhibit

13:30-16:00 **Roundtable Discussion I: Reports from Asian & Western Pacific Countries: The Current Status of Guidelines and Legislation Related to Research Ethics**

Chairpersons: Sopit Thamaree, Secretary, Forum for Ethical Review Committees in Thailand (FERCIT)
Kenji Hirayama, FERCAP Steering Committee Member, Japan

Panelists: Representatives from Australia, Cambodia, India, Indonesia, Japan, Korea, Laos, Malaysia, Mongolia, Nepal, Pacific Island States, Peoples Republic of China, Philippines, Singapore, Sri Lanka, Taiwan-China, Thailand, Vietnam

Guiding Questions

- Are there local laws, regulations, and guidelines related to ethical review of protocols? What regulatory documents or guidelines are used by ethics committees to review protocols?
- Are current laws and guidelines sufficient to protect human research participants in research?
- Is there a national ethics committee? What is its relationship to state authorities? What is its current organizational structure and functions?
- What are the current modes of structural and functional relationships between national health authorities and other ethics committees in each country? Are ethics committees registered/accredited by state authorities?

- What is the role of ethics committees in the national health research system and the implementation of the national research agenda?
- What is the role of ethics committees related to guideline formulation and national legislation?
- What steps should be undertaken to improve ethical review of research in each country?

16:00-16:15 Coffee/Tea Break

16:15-18:00 **Parallel Session 1: Developing Research Guidelines for the Vulnerable Population**

The parallel sessions highlight concepts, case studies, research results, and experiences related to research ethics. The outcomes of the parallel sessions will be considerations on specific guidance for various types of researches.

Activities during the Parallel Sessions:

a. Paper Presentation

b. Position Papers for Guideline Formulation

Session A: HIV-AIDS Research

Chairperson: Representative, Paediatric AIDS Foundation,

Session B: Children as Research Subjects

Chairperson: WHO/IVR Representative

Session C: Ensuring Care in Research for Critically Ill Patients

Chairperson: WHO Representative

Session D: Research on Refugees and Victims of Wars and Disasters

Chairperson: WPRO Representative/ Migration Health, International Organization for Migration (IOM)

Day 2: Tuesday, 13 December 2005

8:00 – 9:00 **Group Reports from Parallel Sessions: Proposed Guidelines for the Vulnerable Population**

Plenary Session 3: Perspectives on the Role of the Government in the Development of National Health Research Systems

Chairpersons: Gopal P. Acharya, Chairman, Nepal Health Research Council, Kathmandu, Nepal
Ock-Joo Kim, Secretary, Korean Association of the Institutional Review Boards (KAIRB)

9:00 - 9:20 **The Role of Health Research Ethics in National Healthcare Programs**
Samlee Plianbangchang, *Southeast Asia Regional Director, WHO*

9:20 - 9:40 **Addressing the 10/90 Gap: The Role of National Health Authorities**
Rob Ridley, Director, Special Programme for Research and Training in Tropical Diseases

9:40 – 10:00 **National Health Research Priority Setting: Strategies towards a Relevant Research Agenda**
Mary Ann Lansang, Board Member, Special Programme for Research and Training in Tropical Diseases

10:00 – 10:20 **Health Resource Allocation and Research Ethics**
Viroj Tangchareonsathien, Senior Researcher, Health Systems Research Institute, Ministry of Public Health, Thailand

10:20 – 10:40 **Defining the Role of Regulatory Agencies in Health Research**
Melody Lin, Deputy Director and International Director, Office for Human Research Protections, Department of Health & Human Services, USA

Coffee/Tea Break

Plenary Session 4: Sharing Responsibilities: Defining the Role of Ethics Committees in the Development of National Quality in Human Research Protections

Chairpersons: Benjamin Kuo, FERCAP Steering Committee Member and Secretary General, Forum for Institutional Review System in Taiwan (FIRST)
Beat Widler, Head of PDQ, Roche Pharmaceuticals, Basel, Switzerland

10:40 - 11:00 **The Development of a National Forum for Good Clinical Practice**
Dhananjay Bakle, Indian Forum for Good Clinical Practice (InFo GCP)

11:00 – 11:20 **Empowering Communities: Sharing Ethical Responsibilities with Research Participants Communities**
Duduzile Biyela, Chairperson, Community Advisory Board, Africa Centre for Health & Population Studies, South Africa

11:20 – 11:40 **The Socio-Political Functions of Ethics Committees in Developing Countries: Expanding Roles and Expectations**
Cristina E. Torres, FERCAP Coordinator

11:40 – 12:00 **Strategies for Strengthening National Ethical Review Systems**
Marcel Kenter, Executive Director, Central Committee for Research Involving Human Subjects (CCMO), The Netherlands

12:00 – 12:20 **Ensuring Relevance and Quality in Research: The SIDCER Assessment and Recognition Process**
Juntra Karbwang, Clinical Coordinator, Special Programme for Research and Training in Tropical Diseases (WHO/TDR)

12:20 - 1230 Discussion

12:30 – 13:30 Lunch

13:30 – 15:30 **Parallel Session 2: Developing Relevant Research Guidance for Special Types of Research**

Session E: Biotechnology
Chairperson: Nancy Hathaway, PATH
Session F: Genetic Research
Chairperson: Representative from India
Session G: Stem Cell Research
Chairperson: Researcher from Korea
Session H: Traditional Medicine
Chairperson: Representative from China

15:30 – 16:00 Coffee / Tea Break

16:00 – 16:30 **Group Reports from Parallel Sessions: Considering the Need for Guidance in Special Types of Research**

Chairpersons: Jie Chen, Professor, School of Public Health, Fudan University, Shanghai, China

Reijo Salmela, Officer for Situation Analysis for Policy
WHO Western Pacific Regional Office

16:30 – 16:50 **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
Francis P. Crawley, Secretary General, European Forum for Good Clinical Practice (EFGCP)

16:50 – 17:00 Closing Remarks
Vichai Chokevivat, Chairman, Forum for Ethical Review Committees in Asia & the Western Pacific (FERCAP)