



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

**FERCAP NEWSLETTER**

**March 31, 2009**

## 2008 ANNUAL CONFERENCE AT A GLANCE



The FERCAP annual conference was held in Rama Gardens Hotel in Bangkok, Thailand on November 24-25, 2008 with approximately 250 participants, mainly from Asia and the Western Pacific region and from other parts of the world. The objective of the conference was to explore and identify various models and mechanisms that will empower stakeholders in health research to contribute to human participant protection. There were various plenary sessions that examined important topics for discussion. Panel discussions from area representatives were also used for information exchange.

The conference contributed to better awareness, knowledge, and practice about empowerment for better human participant protection. Specifically, the conference achieved the following:

- Described the roles, responsibilities, and initiatives by sponsors to empower stakeholders in health research.
- Described programs and initiatives to empower health research investigators for better human subject protection.
- Described programs and initiatives to empower Ethics Review Boards/Committees to contribute to sustainable human participant protection programs.
- Described empowering models and practices of regulatory systems that may be replicated in various country settings.
- Explored effective measures to empower participants in health research.
- Identified gaps, facilitators, and barriers to empowering systems in health research.

- Suggested options and future direction of empowerment systems to maintain the highest ethical standards in health research.
- Developed relevant Asian models of ethical research infrastructure that promotes empowerment within the context of diverse Asian cultures alongside pluralistic socio-economic-political systems.

The speakers came from the ranks of academicians, ethics committee members, research investigators, sponsors, regulators and the TDR Empowerment Unit.

Greg Koski defined the responsibilities of stakeholders in research through a duty-based ethics, by using the perspective of Immanuel Kant who said, "Act in such a way that you treat humanity, whether in your own person or in the person of any other, always at the same time as an end and never merely as a means to an end." Koski explained that research with human beings is justified by the good that it brings to society, therefore, all parties to the human research endeavor have an ethical responsibility and moral duty to safeguard the safety, interests and well being of subjects; to ensure the quality and integrity of the science; to ensure that the benefits to society are realized. Each individual and entity bears a responsibility to acquire the necessary knowledge and training to ensure that one's responsibilities are understood and fulfilled; to commit to conduct one's activities in an efficient and responsible manner; to hold other stakeholders to the same high-level of excellence as they expect from themselves; to work together, collaboratively to fulfill their worthwhile goals and commitments.



Juntra Karbwang-Laothavorn focused her presentation on how to empower researchers and entities in health research. Empowerment involves training of individuals for them to utilize their research capabilities to its fullest. It also requires collective development of ability to initiate, manage and direct research from within institutions and countries, with self-generated resources. Empowerment can also be understood in terms of assisting others in voicing their needs and interests, and in building their own capacity to address those needs and interests in health research. Finally, empowerment can be seen as bringing out the best in oneself, bringing out the best in others, and insisting on our shared responsibilities. WHO/TDR's new vision is "Leadership & Sustainable Capacity for Health Research in DECs" with the goal of empowering researchers and entities in health research in Disease Endemic Countries (DECs).

### Sixteen New Ethics Committees Recognized

Dr. Robert Ridley, WHO-TDR Director, awarded the plaques of SIDCER recognition to sixteen Ethics Committees on November 26, 2008 for their compliance with international and national guidelines/regulations.

The institutions who received the honors were distributed as follows: Six from Thailand: Faculty of Tropical Medicine EC, Mahidol University; Joint Research Ethics Committee; Faculty of Medicine REC, Chiangmai University; Research Institute for Health Sciences HEC, Chiangmai University; Khon Kaen University EC; Health Science Group ERC, Chulalongkorn University. Five from Taiwan: Cathay General Hospital IRB; Taipei Medical University Wanfang Municipal Hospital IRB; Buddhist Tzu Chi General Hospital IRB; Kaohsiung Veterans General Hospital IRB; Mackay Memorial Hospital IRB. Four from Korea: Hallym Sacred Heart Hospital IRB; Daegu Medical Center IRB; Kyung Hee University Hospital IRB; Ajou University Hospital IRB. One from China: Fudan University Huashan Hospital IRB. The recognition of the Joint Institutional Review Board (JIRB) of Taiwan was also renewed.

The annual meeting of the Network of Asian Recognized Ethics Committees (NAREC) was held on the same day and it was presided over by Li-Heng Pao, a representative from the Tri-Service Hospital IRB in Taiwan. He was ably assisted by Benjamin Kuo, NAREC Coordinator. All NAREC members have become FERCAP institutional members upon payment of institutional membership fees. The official website of NAREC is as follows: [www.narec-fercap.org](http://www.narec-fercap.org)



### Incoming FERCAP Chair Elected



Professor Dr. Kenji Hirayama was elected as incoming FERCAP Chair during the FERCAP General Assembly held on November 26, 2008 and presided over by FERCAP current FERCAP Chair, Dr Vichai Chokevivat.

Dr. Hirayama is Dean of the Nagasaki University Institute of Tropical Medicine and member of the FERCAP Steering Committee. His term will start in 2010.

### FERCAP Recent Activities

#### FERCAP Main Activities

24-26 November 2008

- *International Conference on Empowering Stakeholders in Health Research: Towards Developing an Ethics of Accountability and Responsibility*, Rama Gardens Hotel, Bangkok, Thailand [Organized with support from UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) in cooperation with WHO SEARO & WPRO; Institute for Development of Human Research Protection (IHRP); Health Systems Research Institute (HSRI); Forum for Ethical Review Committees in Thailand (FERCIT); and Faculty of Allied Health Sciences, Thammasat University - Rangsit]

28-30 November 2008

- *Resurvey of Royal Thai Army Medical Department IRB*, Rajthivee, Bangkok, Thailand  
Lead Surveyor: Hwei-Ling Lee  
Co-Surveyors: Cristina Torres, Ramesh Acharya  
Survey Coordinator: Juntra Karbwang-Laothavorn

9-11 December 2008

- *Human Participant Protection and Good Clinical Practice Training*, National Institute of Public Health (NIPH), Phnom Penh, Cambodia [Organized with support from WHO WPRO]

18-20 December 2008

- *Human Participant Protection Training*, Huashan Hospital, Fudan University, Shanghai, China [Organized with Huashan Hospital, Fudan University]
- *Launching of China Initiative for Developing Capacity in Ethical Review (CIDCER)* -- a network of China ECs/IRBs working for the SIDCER Recognition Program based in Huashan Hospital, Fudan University, Shanghai, China

23-26 February 2009

- *Survey of Tata Memorial Hospital IRB*, Parel, Mumbai, India [Organized with support from WHO SEARO]  
Lead Surveyor: Hsiang Ning Luk  
Co-Surveyors: Cristina Torres, Roli Mathur  
Survey Coordinator: Cristina Torres

- Survey of King Edward Memorial Hospital IRB, Parel, Mumbai, India [Organized with support from WHO SEARO]  
Lead Surveyor: Sirinart Vasanavathana  
Co-Surveyors: Ramesh Acharya, Paul Kumaran  
Survey Coordinator: Cristina Torres

2-4 March 2009

- *Human Participant Protection Training*, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand [Organized with the support of the Faculty of Medicine, Chulalongkorn University]

## FERCAP Collaborative Activities

19-21 January 2009

- *Workshop on Research Work to International Publication [Manuscript Writing and Scientific Publication Ethics]*, Springfield Beach Resort, Cha-Am, Petchaburi, Thailand [Collaboration with the Faculty of Dentistry, Mahidol University (MU), Bangkok, Thailand]



26-28 January 2009

- Pre-Survey of the Ministry of Health EC, Zanzibar, Tanzania [collaboration with PABIN with support from WHO-IVR]

18 March 2009

- *Sri Lanka Medical Association 122<sup>nd</sup> Annual Scientific Meeting Pre-Congress Workshop on Ethics of International Collaborative Research*, Faculty of Medicine, University of Colombo, Sri Lanka [collaboration with Sri Lanka Medical Association; University of Colombo, Sri Lanka; University of Durham, UK]  
Speakers from FERCAP: Harun Ar-Rashid, Vajira Dissanayake, Shri Krishna Giri, Vasantha Muthuswamy, Cristina Torres

## FERCAP Participation in Various Activities

9-17 February 2009

- *Meeting on the Harmonization of Short Training Courses on GCP-GCLP/Basic Research/Bioethics/Product Research and Development/Quality Management/PPM/Social Sciences/Clinical Data Management*, WHO-TDR Clinical Coordination and Training Center (CCTC), Thammasat University - Rangsit, Pathumthani, Thailand [Organized by WHO-TDR]

22-25 March 2009

- *GCP Inspection and Audit Findings Roundtable Discussion*, Berlin, Germany [Organized by the Drug Information Association (DIA)]  
FERCAP Representative: Cristina Torres

- *21<sup>st</sup> Annual DIA EuroMeeting*, Berlin, Germany [Organized by DIA]  
FERCAP Representative: Cristina Torres  
Presentation Topics: (a) International GCP Inspection Experience; (b) Clinical Trials in Third Countries

## FERCAP Activities for the Next Quarter

13-15 April 2009

- *Human Participant Protection Training*, National Institutes of Health, University of the Philippines, Manila, Philippines

21-23 April 2009

- *Standard Operating Procedures Training*, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand

6 May 2009

- *Ethics in Social Behavior Research Workshop*, Tri-Service General Hospital, Taipei, Taiwan

7-13 May 2009

- Survey of China Medical University Hospital IRB, Taipei, Taiwan
- Survey of Academia Sinica IRB, Taipei, Taiwan

15-17 May 2009

- *Standard Operating Procedures Training*, Huashan Hospital, Fudan University, Shanghai, China

18 May 2009

- Pre-Survey of Jiangsu Province Hospital, Jiangsu, China

24-30 May 2009

- FERCAP Steering Committee Meeting, Seoul, South Korea
- Resurvey of Asan Medical Centre Hospital IRB, Seoul, South Korea
- Resurvey of Seoul National University Hospital (SNUH) IRB, Seoul, South Korea
- Survey of Kangbuk Samsung Hospital IRB, Seoul, South Korea
- Survey of Inha University Hospital, Incheon, South Korea

22-25 June 2009

- Survey of the National Institutes of Health Research and Development IRB, Jakarta, Indonesia

29 June-3 July 2009

- *Regulatory Authorities Training*, Bureau of Food and Drugs, Manila, Philippines

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