

11<sup>th</sup> FERCAP International Conference  
*Innovation, Integration and Ethical Health Research*

VENUE  
Hotel Inter-Burgo  
Daegu, South Korea

SCHEDULE  
Pre-Conference Training – November 20, 2011  
Conference – November 21-22, 2011  
FERCAP and NAREC General Assembly – November 23, 2011



Forum for Ethical Review Committees in Asia  
& the Western Pacific



Strategic Initiative for Developing Capacity in Ethical Review

hosted by



**대구가톨릭대학교의료원**  
DAEGU CATHOLIC UNIV. MEDICAL CENTER

with support from



CIMI (Comprehensive and Integrative Medicine Institute)

Medi-City Daegu (Daegu Medi-Cluster)

**Conference Registration:**

November 20, 2011 13:00 – 17:00

November 21, 2011 07:30 – 09:00

**Introduction**

The advent of new technologies, new products, and new interventions has raised new ethical concerns in research. The current research environment is further complicated by a growing interest in natural methods, traditional as well as complementary interventions that may address specific health concerns. The combination of the new approaches with the traditional methods creates more possibilities of effective interventions to treat diseases and improve the health of the population. Innovative techniques, new research methodologies together with traditional approaches from different cultures present greater challenges to ethics review committees that are mandated to provide for safety nets to protect human participants in research.

The 11th Annual FERCAP Conference will provide a forum for various stakeholders to discuss innovative concepts and models as well as integrative initiatives that combine new techniques with traditional and existing models related to the ethical conduct of research. The goal is to inform various stakeholders such as ethics committee members, regulators, and researchers related to state of the art knowledge about innovation and integration to be able to identify the address ethical challenges when such techniques are involved in research. The goal is to provide opportunities for dialogue among individuals and networks of ethically motivated, adequately informed, and responsible stakeholders who regularly communicate and interact with one another to assure the public about the protection of the rights and safety of human participants in the conduct of research.

Through plenary sessions and panel presentations, group discussions and reports, the full range of partnership and alliance issues and best practices towards sustainability will be explored.

**Objectives**

- To describe innovative concepts, practices, and initiatives related to the ethical conduct of research
- To identify good ethical practices in innovative and integrative health research
- To identify gaps, facilitators, and barriers to ethical research and good research practices related to innovation and integration
- To suggest options and future directions of national ethical research systems to maintain the highest ethical standards related to innovation in health research
- To develop relevant models of good ethical review practices and procedures within the context of diverse Asian research environments related to a wide range of innovative and integrative initiatives and concerns

**Conference Participants**

The conference participants come from the various sectors and disciplines involved in health research, mainly from Asia and the Western Pacific region. International

representatives from national health authorities, ethics committees, researchers, research participants, academic institutions, and the pharmaceutical industry will share their ideas and actual experiences to elucidate the conference theme.

**Conference Outcome**

The conference should be able to contribute to better awareness, knowledge, and practice related to leading concepts and practices in innovation and integration in health research.

## FERCAP 2011 Conference Agenda

### Day 1: November 21, 2011 (Monday)

**09:00-10:00 Opening Ceremony**

Chairpersons: Kenji Hirayama, Nagasaki University, FERCAP Chairperson  
Young Mo Koo, FERCAP Vice-Chairperson

**Welcome Remarks**

*Rev. Jun-Woo Kim, President, Daegu Catholic Univ. Medical Center*  
*Hahn-Koo Lee, Member, Korean National Assembly*  
*Bum-il Kim, Mayor, Daegu Metropolitan City*  
*You Seung Kim, President, Daegu Medi-Cluster*

**Introduction of Guests/Delegation**

**Keynote Address**

**Building a Global Network in Clinical Health Research in Support of Innovation and Integration**

*Greg Koski, Harvard University*  
*Advisory Board Chair, Strategic Initiative towards Developing Capacity in Ethical Review (SIDCER)*

**10:00-10:30 Coffee/Tea Break**

**10:30-11:45 Session 1: Describing the Environment for Innovation and Integration towards Ethical Health Research**

Chairpersons: Aphornpirom Ketupanya, Forum for Ethical Review Committees in Thailand and FERCAP Steering Committee  
Ho Gak Kim, Daegu Catholic Univ. Medical Center IRB

**The Challenge of Conducting Medical Research Across Different Philosophic (Healing) Traditions**

*Stephen Rosenfeld, Olympia, Washington*

**Promoting Trust in Health Research: A European Perspective on Integrating Innovation and Research Ethics into Patient and Community Needs**

*Francis Crawley, Good Clinical Practice Alliance – Europe and SIDCER Steering Committee*

**The Current Mechanisms in LMIC and Potential Role of Research Ethics Committees in Health Research Governance**

*Manju Rani, World Health Organization Western Pacific Region*

Open Forum

**11:45-13:00 Session 2: Strengthening Regulatory Compliance in Ethical Health Research**

Chairpersons: Vajira Dissanayake, University of Colombo, Sri Lanka and FERCAP Steering Committee  
Hyun Il Choi, Sam Women's Hospital and Korean Association of IRBs (KAIRB)

**International Cooperation and the European Medicines Agency Reflection Paper on Ethical and GCP Aspects of Clinical Trials Conducted in Third Countries**

*Danielsson Gunnar, Medical Products Agency*

**Improving US FDA Global Oversight of Clinical Trials for Better Human Subject Protection**

*Leslie K. Ball, Center for Drug Evaluation and Research Director, US Food and Drug Administration (FDA)*

**Ensuring Ethical Health Research in Clinical Trials in Korea**

*Young-ok Kim, Clinical Trials Management Division Director, Korean Food and Drug Administration*

Open Forum

**13:00-14:00 Lunch Break**

**14:00-15:30 Session 3: Dealing with Innovation/Developments in Ethical Health Research**

Chairpersons: Vicente Belizario, Jr., National Institutes of Health, University of the Philippines and FERCAP Steering Committee  
Duk Yoon Kim, Daegu Catholic Univ. Medical Center (DCUMC) IRB

**Possible Changes to the US IRB Regulations: HHS Advance Notice of Proposed Rulemaking (ANPRM)**

*David Forster, Western Institutional Review Board*

**Regulating the Use of Exculpatory Language in Consent Forms**

*Melody Lin, US Office for Human Research Protection*

**Risk-based Quality Management in Clinical Trials**

*Danielsson Gunnar, Medical Products Agency*

**The Strategic Plans for IRBs in South Korea**

*Young Hun Jeong, Director, Division of Bioethics and Safety, Korean Ministry of Health and Welfare*

Open Forum

**15:30-16:00 Coffee/Tea Break**

**16:00-17:30 Session 4: Improving National Ethical Review Systems**

Chairpersons: Hee Young Shin, Chonnam University Hospital IRB, Korea  
Magdalena Agtini, National Institutes for Health Research and  
Development, Indonesia and FERCAP Steering Committee

**Strengthening International Networking: The Future of SIDCER**  
*Vichai Chokevivat, SIDCER Chair*

**The National Research Council of Thailand and IRB Accreditation**  
*Sopit Thamaree, Chulalongkorn University Faculty of Medicine IRB,  
Thailand*

**Developing a National Accreditation System and Quality  
Improvement of Research Ethics Committees**  
*Marita V. T. Reyes, Philippine Health Research Ethics Board*

**Improving Access to Safety Information from Stakeholders in  
Clinical Trials**  
*Aphornpirom Ketupanya, Forum for Ethical Review Committees in  
Thailand (FERCIT)*

Open Forum

**18:30 Welcome Dinner**

**Day 2: November 22, 2011 (Tuesday)**

**08:30-10:00 Session 5: Social and Community Issues in Ethical Health Research**

Chairpersons: Sopit Thamaree, Chulalongkorn University Faculty of Medicine IRB, Thailand  
Oh Dae Kwon, Daegu Catholic Univ. Medical Center (DCUMC) IRB

**Innovation, Integration and Ethical Health Research in Family-to-Family Project on Psychoeducation to Improve Children's Outcomes in HIV+ Families: The Experience of Chiangsaen Hospital**

*Wacharin Chaitha et al., Chiangsaen Hospital, Thailand*

**Ethical Issues in Neurobehavioral Research in Developing Countries**

*UK Misra, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India*

**Clinical Research in India: Perspectives from the Site**

*Vajira Dissayanake et al., University of Colombo, Sri Lanka*

**Engaging Communities in Health Research: A Qualitative Study of the Tak Province Community Ethics Advisory Board**

*Phaik Yeong Cheah, Khin Maung Lwin, et al., Mahidol Oxford Tropical Medicine Research Unit*

Open Forum

**10:00 10:30 Coffee/Tea Break**

**10:30-12:00 Session 6: Addressing Issues in Different Types of Ethical Review**

Chairpersons: Hejian Zou, Huashan Hospital IRB, Fudan University, China and FERCAP Steering Committee  
Sang Ho Yoo, Hallym Sacred Heart Hospital IRB

**Promotional Strategy of Daegu-Gyeongbuk Medical Cluster: Development Directions of the Medical Device**

*Sung-Ho Eun, Director General, Daegu-Medi Cluster*

**Challenges in Ethical Review of Traditional Medicine Protocols in China**

*Xiuqin Wang and Xiong Ningning, Jiangsu Provincial Hospital of Traditional Chinese Medicine, China*

**Challenges for Reviewers of International Genomic Research**

*Susan Bull, The Ethox Centre, University of Oxford*

**Assessment of the Conduct of Informed Consent in Rural Areas in India**

*Subhash Yadav et al., Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India*

Open Forum

**12:00-13:00 Lunch Break**

**13:00-14:30 Session 7: Areas for Capacity Building of Ethics Review Committees**

Chairpersons: Chih Shung Wong, Taiwan Association of IRBs  
Im Hee Shin, Daegu Catholic Medical University, Korea

**Findings of Sponsor Audits of Ethical Review Committees: Areas for Improvement**

*Lisa Hamadian, Roche Product Pty. Limited*

**Addressing Administrative Issues and Ethical Review Practices in Innovative Clinical Medical Research**

*Jin Huang, Jin-hong Hu, Yao-jun Xiang, Changhai Hospital EC, Shanghai, China*

**Developing a Specialized Assessment Tool for Social Science Research**

*Cristina E. Torres, Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP)*

**Supporting Ethical Review of International Multi-Center Research**

*Susan Bull, Global Health Reviewers, University of Oxford*

Open Forum

**14:30-15:00 Coffee/Tea Break**

**15:00-17:00 Session 8: Addressing IRB Issues at Various Levels**

Chairpersons: Juntra Karbwang, World Health Organization  
Marita V. T. Reyes, Philippine Health Research Ethics Board

**Improving Human Subject Protection at the Institutional Level**

*Ock-joo Kim, Seoul National University IRB*

**Improving National Networks of IRBs in Korea**

*Suk-Koo Lee, President, Korean Association of IRBs (KAIRB)*

**Strengthening National Networks of IRBs: The Indian Experience**

*Medha Joshi, Tata Memorial Hospital IRB, Mumbai, India*

Open Forum

**Closing Remarks**

*Kenji Hirayama, FERCAP Chair*



**PRE-CONFERENCE Training: November 20, 2011 (Sunday) 13:00 – 17:00**

**Agenda**

**Improving Conduct of Research Ethics Committee Meetings**

Topics:

- Elements of Good Quality Review *Cristina E. Torres*
- Elements of a Comprehensive Board Meeting Agenda/ Minutes  
*Edlyn Jimenez*
- Elements of Good Board Meeting Discussion *Juntra Karbwang*
- Mock Review *Vichai Chokevivat (Chair)*
- Analysis *Cristina E. Torres*

**FERCAP GENERAL ASSEMBLY: November 23, 2011 (Wednesday) 8:30 – 12:00**

**Agenda**

- 8:30-9:00**      **Opening Remarks**      *Kenji Hirayama, FERCAP Chair*
- FERCAP Annual Report**      *Cristina E. Torres, FERCAP Coordinator*
- 9:00-11:00**      **SIDCER/FERCAP Recognition Ceremony**      *Arthur Navarro (Emcee)*
- 11:00-12:00**      **Country/Area Meetings: Strengthening the FERCAP/NAREC Networks**
- ECs/IRBs Surveyed (November 2010-November 2011)**

**FERCAP/SIDCER Surveyed ECs/IRBs (November 2010-November 2011)**

**CHINA**

- Renji Hospital EC, Shanghai
- IRB of Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine, Shanghai
- Sun Yat-sen University Cancer Center IRB, Guangzhou
- IRB of Shanghai Mental Health Center, Shanghai
- Huashan Hospital IRB, Fudan University, Shanghai (renewal)
- Peking University First Hospital National Unit of Clinical Trial EC, Beijing
- IRB of The First Affiliated Hospital of Henan College of Traditional Chinese Medicine, Zhengzhou
- Clinical Trial EC of Zhong Shan Hospital, Fudan University, Shanghai

**INDIA**

- IEC of Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow

## **INDONESIA**

- Komisi Etik Penelitian Kesehatan Fakultas Kedokteran Universitas Hasanuddin (Faculty of Medicine, University Hasanuddin EC), Makassar

## **SOUTH KOREA**

- Daegu Catholic University Medical Center IRB, Daegu (renewal)
- Hallym University Sacred Heart Hospital IRB, Anyang (renewal)
- Ajou University Hospital IRB, Suwon (renewal)
- Soon Chun Hyang University Bucheon Hospital IRB, Bucheon
- Korea University Guro Hospital IRB, Seoul
- Gachon University Gil Hospital IRB, Incheon

## **TAIWAN**

- Mackay Memorial Hospital IRB, Taipei (renewal)
- Joint Institutional Review Board, Taipei (renewal)
- Taipei City Hospital IRB, Taipei
- Cathay General Hospital IRB, Taipei (renewal)
- Buddhist Tzu Chi General Hospital – Hualien IRB (renewal)
- Kaohsiung Veterans General Hospital IRB (renewal)
- Kaohsiung Kai-Suan Psychiatric Hospital IRB

## **THAILAND**

- EC of the Faculty of Tropical Medicine, Mahidol University, Bangkok (renewal)
- The ERC for Research Involving Human Research Subjects, Health Science Group, Chulalongkorn University, Bangkok (renewal)
- Khon Kaen University EC for Human Research (KKU EC) (renewal)
- Faculty of Medicine Research EC, Chiang Mai University (renewal)
- Research Institute for Health Sciences (RIHES) HEC, Chiang Mai University (renewal)