11th 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
Magdarina 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, Shanghai 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 Chokeyvivat (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)