



Forum for Ethical Review Committees in Asia and the Western Pacific

FERCAP NEWSLETTER

February 15, 2010

2009 Annual FERCAP Conference Held in Chiangmai, Thailand



2009 Annual FERCAP Conference, Nov. 23-25, Chiangmai, Thailand

The 9th Annual FERCAP International Conference was held at the Imperial Mae Ping Hotel in Chiangmai, Thailand, on November 23-25, 2009 with the theme "Developing Leadership in Health Research: Towards Good Practices and Integrated Systems." The international conference speakers included representatives from various GCP stakeholders led by Leslie Ball from the US Food and Drug Authority, Pierre Henri Bertoye from the French Inspectorate, Beat Widler of Roche, Kenji Hirayama from Nagasaki University, Urmila Thatte from India, and Chitr Sitthi-amorn from Thailand. The various speakers explained the current state of the art perceptions and practices related to standards and good performance in health research. A summary of points discussed for each session is as follows:

Session 1: Defining Ethical Leadership in Health Research towards Developing a Framework for Good Practice

Leadership in health research refers to professional excellence rooted in ethical values. Individuals need emotional and social intelligence to be able to promote the common good. It also requires developing a quality culture system that would serve as an enabling environment for health research stakeholders who are committed to develop relevant interventions to address the health problems of various populations. Tropical disease research is an example of a program that addresses neglected diseases of the poorest sectors of the populations. Product research and development requires collaboration and commitment from various sectors in order to develop relevant products for large segments of humanity.

Session 2: Addressing Gaps in Regulatory Oversight towards Ensuring Good Performance

Drug regulatory agencies from developed countries discussed the challenges they face due to the globalization of clinical trials, the vulnerability of the IRB system, and the need to develop capacity among local regulatory agencies to implement international guidelines and regulations towards credible data and the protection of human participants. The speakers emphasized the need for partnership and cooperation among regulatory authorities of different countries to achieve international harmonization and development of a common framework for ethical and scientific standards so that data can be accepted from different countries. To achieve these goals, there is need for a more vigilant oversight by regulators and effective enforcement of existing regulations.

Session 3: Empowering Ethics Committees towards Leadership in Human Subject Protection

The speakers presented examples of good practices of research ethics committees for more efficient operations, better participation of non-medical members, and better review of the informed consent document. The Dutch Central Research Ethics Committee exercise oversight over local IRBs and accounts for efficient review through proper policies, a centralized structure and an accountable system. The Indian forum for ethics committees (FERCI) has developed educational materials to assist their lay members to understand biomedical research and the ethical issues involved in protocol review. A Korean IRB (Kyung-hee) has developed a glossary of Korean terms that may be used in consent documents and implements a system of editing consent forms for better understanding of research participants. Another Indian speaker highlighted the need to develop an accreditation of ethics committees based on the perception of researchers and participants.

Session 4: Investigator Initiatives towards Leadership in Ethical Health Research

There were two presentations about empirical studies done on the informed consent process, one from India and another from Bangladesh. They highlighted the gap between the perceptions of the researchers and the participants. To improve the process, various methods may be adopted like ensuring more readable forms that contain complete

information, using multimedia techniques, and better interaction between the research team and the participants. There is also a need to improve public awareness about the rights of participants. The survey among researchers showed that they possess the knowledge about the importance of the informed consent process but some had poor attitude to apply it in practice.

The Sri Lanka study about perception of researchers and policy makers about stored samples showed that the respondents found it acceptable to give sample donors the option to provide advance consent to unspecified future research on their samples, under the condition that future research be approved by an ethics committee. The presentation about scientific misconduct discussed their effects in terms of generating media attention, harm to patients, and termination of the project, institutional loss of face, regulatory sanctions and temporary loss of public trust.

Session 5: Institutional/Sponsor Initiatives towards Leadership in Health Research

Sponsor organizations described some good practices that included seeking FERCAP recognition for their institutional review board as a risk management strategy, formation of academic contract research organizations that provided innovative service to industry, and development of useful technology to improve understanding of the consent form and development of educational strategies to assist lay members of ethics committees improve their review functions. Non-compliance by IRBs to GCP requirements were classified by sponsor auditors as major that required corrective action, minor and nuisance that needed voluntary correction. Academic institutions in China formed an association to educate their members and encourage good review practices.

Session 6: Establishing Benchmarks in Improving Community Participation in Health Research

Community advisory boards (CAB) perform various research related functions like providing inputs to research protocols to make them more relevant to community needs, reviewing the community impact of protocols, and members are encouraged to participate in networking and training activities. To improve the functioning of CABs, they need to define their organizational vision, mission, roles, and responsibilities. They need to develop better knowledge about their community in order to participate in a dynamic manner with other stakeholders. Conducting research among indigenous populations requires cultural sensitivity to local customs and traditions and may necessitate community consultation and involvement.

Pharmacovigilance in developed countries involve clinicians, regulatory authorities and patient communities for better monitoring of adverse drug reactions. Developing countries need to improved better surveillance activities for better information and proper action about adverse drug reactions.

New FERCAP Steering Committee

- Chair: Dr. Kenji Hirayama (Japan), Dean of the Institute of Tropical Medicine, Nagasaki University
- Vice Chair: Dr. Young Mo Koo (Korea), Bioethicist and Member, Asan Medical Center, Seoul
- Secretary: Dr. Hejian Zou (China), Chair, Huashan Hospital IRB, Shanghai
- Board Members:
 - Dr. Aphornpirom Ketupanya (Thailand), Chair, Forum for Ethical Review Committees in Thailand
 - Dr. Chien-Jen Chen (Taiwan), Chair of Academia Sineca IRB, Taipei
 - Dr. Magdarina Agtini (Indonesia), Secretary, National Institutes for Health Research and Development IRB, Jakarta
 - Dr. Roli Mathur (India), Scientist, Indian Council for Medical Research, New Delhi
 - Dr. Vajira Dissanayake (Sri Lanka), Secretary, University of Colombo IRB
 - Dr. Vicente Belizario, Jr. (Philippines), Deputy Director, National Institutes of Health, University of the Philippines Manila

- FERCAP Permanent Secretariat:
 - Advisers: Dr. Juntra Karbwang, WHO-TDR, FERCAP Founding Member
Dr. Vichai Chokevivat, SIDCER Chair
 - Treasurer: Dr. Kesara Na Banchang, Director, WHO-TDR Clinical Coordination and Training Center
 - FERCAP Coordinator: Dr. Cristina E. Torres, Social Science Professor
 - FERCAP Research Fellow: Arthur Navarro

Thanks to the Former SC Members

- Chair: Dr. Vichai Chokevivat, Thailand
- Vice-Chairperson: Dr. Benjamin Kuo, Taiwan
- Secretary: Dr. Vasantha Muthuswamy, India
- Treasurer: Dr. Kesara Na-Bangchang, Thailand
- Education Officer: Dr. Xiuqin Wang, China
- Communications Officer: Dr. Marita Reyes, Philippines
- Member Representatives:
 - Dr. Suriadi Gunawan, Indonesia
 - Dr. Ock Joo Kim, Korea
 - Dr. Kenji Hirayama, Japan
 - Dr. Anoja Fernando, Sri Lanka

Twenty-one Asian Ethics Committees Recognized in 2009

Fourteen new Ethics Committees were recognized during the FERCAP General Assembly in Chiangmai, Thailand on November 25, 2009. Seven Ethics Committees also had their recognition renewed during the General Assembly. This latest addition to the list of recognized Ethics Committees brings the total to 53 Asian Ethics Committees recognized under the SIDCER Recognition Program.

The 14 new Ethics Committees recognized were as follows: (1) Ethics Committee of the First Affiliated Hospital, Nanjing Medical University, Jiangsu Province Hospital (China); (2) Ethics Committee for Research on Human Subjects (ECRHS) of SETH G.S. Medical College and King Edward Memorial (KEM) Hospital Institutional Review Board (India); (3) Tata Memorial Centre Human Ethics Committee (TMC-HEC) (India); (4) National Institutes of Health Research and Development (NIHRD) Ethics Committee (Indonesia); (5) Chungnam National University Hospital Institutional Review Board (CNUH-IRB) (South Korea); (6) Inha University Hospital Institutional Review Board (South Korea); (7) International Vaccine Institute Institutional Review Board (IVI IRB) (South Korea); (8) Kangbuk Samsung Hospital Institutional Review Board (South Korea); (9) Ethics Review Committee, Faculty of Medicine, University of Colombo (Sri Lanka); (10) Human Subject Research Ethics Committee/Institutional Review Board-Academia Sinica (HSREC/IRB-AS) (Taiwan); (11) Buddhist Tzu Chi General Hospital - Taipei Institutional Review Board (Taiwan); (12) China Medical University Hospital Institutional Review Board (Taiwan); (13) Shin Kong Wu Ho-Su Memorial Hospital Institutional Review Board (Taiwan); and (14) Siriraj Institutional Review Board (SIRB), Faculty of Medicine, Siriraj Hospital, Mahidol University (Thailand).

The 7 Ethics Committees that had their recognition renewed were as follows: (1) Asan Medical Centre Institutional Review Board (South Korea); (2) Seoul National University Hospital (SNUH) Institutional Review Board (South Korea); (3) Chang Gung Memorial Hospital (CGMH) Institutional Review Board (Taiwan); (4) National Taiwan University Hospital Research Ethics Committee (NTUH REC) (Taiwan); (5) Tri-Service General Hospital (TSGH), National Defense Medical Center Institutional Review Board (Taiwan); (6) Faculty of Medicine, Chulalongkorn University Institutional Review Board (Thailand); and (7) Royal Thai Army Medical Department Institutional Review Board (Thailand). In addition, FERCAP also assisted in the recognition of the Republic of Tatarstan Regional Ethics Committee (Russia) last year and the Faculty of Medicine, Addis Ababa University Institutional Review Board (Ethiopia) and The Armauer Hansen Research Institute (AHRI-ALERT) Ethics Review Board (Ethiopia) this year.

FERCAP at a GLANCE

FERCAP Main Activities

17-20 August 2009

- Ethics Committee of the First Affiliated Hospital, Nanjing Medical University, Jiangsu Province Hospital, China

24-26 August 2009

- Buddhist Tzu Chi General Hospital - Taipei IRB, Taiwan
- Tri-Service General Hospital, National Defense Medical Center IRB, Taiwan

27-29 August 2009

- National Taiwan University Hospital Research EC (NTUH REC), Taiwan
- Chang Gung Memorial Hospital (CGMH) IRB, Taiwan

1-3 September 2009

- Chungnam National University Hospital IRB, South Korea

4-6 September 2009

- International Vaccine Institute (IVI) IRB, South Korea

7-10 October 2009

- Zanzibar Medical Researches Ethical Committee (ZAMEC), Tanzania

12-14 October 2009

- Faculty of Medicine, University of Colombo Ethics Review Committee, Sri Lanka

30 November-2 December 2009

- Taipei Veterans General Hospital IRB, Taipei, Taiwan

3-5 December 2009

- Changhua Christian Hospital IRB, Changhua City, Taiwan

FERCAP Collaborative and Network Activities

3-7 August 2009

- *FERCAP-SIDCER Strategic Quality Management (SQM) Training Workshop* [Organized with WHO-TDR and WHO-TDR CCTC]
WHO-TDR CCTC, Thammasat University (TU) - Rangsit Campus, Pathumthani, Thailand

7-9 September 2009

- *Workshop on Research Work to International Publication* [Organized by the Faculty of Dentistry, Mahidol University]
Springfield@Sea Resort, Cha-Am, Petchaburi, Thailand

1-2 October 2009

- *Regulatory Pathways for Clinical Trials of Dengue Vaccines* [Organized by WHO]
JW Marriott Hotel, Bangkok, Thailand

5-7 October 2009

- *International Course on Research Ethics* [Organized by Thammasat University, University of Bergen, and TCELS]
WHO-TDR CCTC, Thammasat University (TU) - Rangsit Campus, Pathumthani, Thailand

26 October-17 November 2009

- *Diploma Course on Research and Development of Products to Meet Public Health Needs* [Organized by Nagasaki University and Thammasat University]
Institute of Tropical Medicine, Nagasaki University - Sakamoto, Nagasaki, Japan

2010 FERCAP Annual Conference in Shanghai, China

During the General Assembly of the 2009 FERCAP annual conference, Dr Hejian Zou, representing the Chinese Initiative for Developing Capacity in Ethical Review (CIDCER), proposed to host 2010 FERCAP Annual Conference in Shanghai, China.

Dr. Zou's proposal is expected to further contribute to the capacity building of IRBs in China, obtaining recognition from regulatory authorities about the role of IRBs, and promoting the SIDCER/FERCAP initiative in China. As one of the emerging markets, the number of clinical trials is expected to increase and such a situation requires the improvement of ethical review in China. So far, the 4 SIDCER recognized IRBs are taking the leading role in establishing a communication platform to provide learning and sharing opportunity towards the development of ethical review guidelines and training programs for IRB management.

Dr. Zou elaborated in his proposal the strengths for China to host the annual conference. First was government support and he quoted the remarks of Dr. Jian-Guang Xu, the General Director of Shanghai Municipal Bureau, "Public recognition will drive the pursuit of high quality. International recognition of qualifications promotes the implementation of international standards. We will be honored to host the 10th FERCAP Conference in Shanghai, China." CIDCER provision of academic support that facilitates communication and coordination is an essential strength as well.



2011 FERCAP Annual Conference in Daegu, Korea



The 2011 FERCAP Annual Conference will be held in DAEGU, KOREA. In the General Assembly of 9th FERCAP Annual Conference in Chiangmai, Dr. Im Hee Shin, IRB expert member of Daegu Catholic University Medical Center (DCUMC), proposed to host the 11th FERCAP annual conference. As one of the biggest cities of Korea, the Medi-City Daegu has become a center of the energy industry and host to IAAF World Championship in Athletics in 2011, Summer Universiade in 2003, FIFA World Cup in 2002, and other international conferences. Daegu remains as a traditional city with advanced medical facilities and highly skilled medical infrastructure.

Recently, the Korean government decided to develop a high-technology medical complex in Daegu as part of its strategic plan that will focus on new medicines, innovative medical devices, and equipment. It was emphasized that for purposes of research and development, the clinical trial environment should be developed together with IRB development. By 2011, all hospitals in Daegu will be surveyed and recognized by FERCAP.

FERCAP Annual Conference

*Developing Leadership in Ethical Health Research
Towards Good Practices and Integrated Systems
Chiangmai, Thailand, 23-24 November 2009*

For more information about the conference, visit:

www.fercap-sidcer.org/home.asp

FERCAP Newsletter

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