



Forum for Ethical Review Committees in Asia and the Western Pacific

FERCAP NEWSLETTER

July 31, 2009

FERCAP at WHO-TDR CCTC



WHO-TDR Short Course on Immunology and Vaccinology Applied to Dengue Infection, WHO-TDR CCTC, 4-8 May 2009

The new FERCAP office is located at the WHO-TDR Clinical Coordination and Training Center (CCTC) at Thammasat University (TU) - Rangsit Campus. The WHO-TDR CCTC is a joint initiative between WHO-TDR and TU that aims to establish a leading service provider and catalyst for the development of quality and ethical health research. WHO-TDR Scientist and FERCAP Founding Member Prof. Dr. Juntra Karbwang-Loathavorn, TU Faculty of Allied Health Sciences (FAHS) Dean Prof. Dr. Vithoon Viyanant, and TU FAHS Deputy Dean and FERCAP Treasurer Prof. Dr. Kesara Na-Bangchang were the focal persons who facilitated the formation of the center and Prof. Dr. Kesara serves as its first Director.

The center conducts and facilitates training in health research ethics, good clinical practice (GCP), good clinical laboratory practice (GCLP), and clinical data management. FERCAP Coordinator Dr. Cristina Torres and FERCAP Research Fellow Arthur Navarro have been actively involved in the programs and projects of WHO-TDR CCTC. On February 9-17, 2009 FERCAP participated in the Workshop on the Harmonization of WHO-TDR Short Training Courses where the health research ethics modules were standardized. Dr. Juntra Karbwang-Loathavorn presented about the quality and ethical requirements in developing dengue vaccine during the WHO-TDR Short Course on Immunology and Vaccinology held last May 4-8.

Dr. Glenn Laverack and Dr. Pascal Launois of the WHO-TDR Empowerment Unit visited the center on May 29-30 to discuss further the partnership with the various programs of the center. Last June 4-8, the strategic plan of the center was developed during the Total Quality Management (TQM) Training Workshop. FERCAP also took part in the GCP Short Courses held on July 20-31.

CIDCER-FERCAP in China

The China Initiative for Developing Capacity in Ethical Review (CIDCER) was launched on December 21, 2008 by IRB members from the Second Military Medical University Shanghai Changhai Hospital, the Affiliated Hospital of Nanjing Traditional Chinese Medicine University, and the Shanghai Huashan Hospital Fudan University. Its mission is to establish a communication platform for IRBs to promote the exchange of information and experiences towards sound and sustainable development of ethical review practice. More than 20 Chinese institutions registered to join the forum. Another meeting was held on May 16, 2009 at the Huashan Hospital where the participants agreed that member institutions will take turns hosting the forum meetings. Upcoming topics will include challenges in ethical review and updated information on guidelines and regulations. In September, the Affiliated Hospital of Nanjing University of Traditional Chinese Medicine will host the 2nd forum. The "Ethical Review of Medical Device Studies" will be the main topic for discussion.

The Shanghai Huashan Hospital WHO-TDR-FERCAP Training Center in GCP & Research Ethics Training Center organized a two-day training on "Developing Standard Operating Procedures for IRBs" on May 15-16. This training focused on developing IRB SOPs within the framework of international guidelines and national regulations and improving the quality of ethical review. The faculties were drawn from the Shanghai Food and Drug Administration, the Second Military Medical University Changhai Hospital, the Affiliated Hospital of Nanjing Traditional Chinese Medicine University, the Shanghai Huashan Hospital Fudan University, and FERCAP.

The participants learned how to apply ethical principles in the review practice by observing a mock board meeting and conducting a site visit of the Huashan IRB Office. The trainees, who were responsible for the management of clinical trial institutions and/or IRB management, came from 12 provinces across the China. They found the training to be useful and instructive for their daily work.

On August 21-23, the Affiliated Hospital of Nanjing University of Traditional Chinese Medicine will host the National Continuing Medical Education Programme on "Advanced Training for IRB SOP & Review of Research Protocols." The training will discuss both the scientific issues and ethical issues involved with human subject



"Developing Standard Operating Procedures for IRBs" Training
Shanghai Huashan Hospital Fudan University , 15-16 May 2009

research that include scientific design of research protocols, scientific issues related to clinical research in Chinese medicine, animal efficacy experiment, toxicity issues in clinical research, risk and benefit assessment, informed consent exemption, vulnerability, and SAE management.

The training program will serve as the first academic workshop of the Hospital Ethics Committee Society branch of the Nanjing Hospital Association to strengthen capacity in research ethics in Jiangsu province. On August 17-20, FERCAP will conduct a training and survey of Jiangsu Provincial Hospital, in Nanjing, China.

FERCAP at a GLANCE

FERCAP Main Activities

24 May 2009

- FERCAP Steering Committee Meeting
Somerset Place, Seoul, South Korea

Training

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

9 May 2009

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

12 May 2009

- Ethics in Social Behavior Research
Chi-Mei Medical Center, Tainan, Taiwan

15-17 May 2009

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

18-19 June 2009

- GCP Training for Investigators:
National Institutes of Health, University of the Philippines, Manila, Philippines

6-9 July 2009

- Standard Operating Procedures Training
National Institutes of Health, University of the Philippines, Manila, Philippines

IRB/EC Survey

7-13 May 2009

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

18 May 2009

- Jiangsu Province Hospital, Jiangsu, China
[Pre-Survey of EC/IRB organized with CIDCER]

24-30 May 2009

- Asan Medical Centre Hospital IRB, Seoul, South Korea
- Seoul National University Hospital (SNUH) IRB, Seoul, South Korea
- Kangbuk Samsung Hospital IRB, Seoul, South Korea
- Inha University Hospital, Incheon, South Korea

13-16 July 2009

- National Institutes of Health Research and Development (NIHRD) IRB, Jakarta, Indonesia

21-24 July 2009

- Siriraj IRB, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand

27-1 July/August 2009

- Lee Women's Hospital IRB, Taichung, Taiwan
- Shing Kong Wu Ho-Su Memorial Hospital IRB, Taipei, Taiwan

Upcoming Activities

3-7 August 2009

- SIDCER-FERCAP Strategic Quality Management (SQM) Training Workshop
WHO-TDR CCTC, TU - Rangsit Campus, Thailand

1-2 October 2009

- Ethics and Regulation of Dengue Vaccine Development
Bangkok, Thailand

23-24 November 2009

- FERCAP Annual Conference
Chiangmai, Thailand

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

Call for Abstract Submission

Deadline for Abstracts: August 30, 2009
Submit to: fercap.sidcer@yahoo.com

For more information:

http://www.fercap-sidcer.org/new_web/doc/2009/FERCAP_Conference_2009_Call_for_Abstracts2.pdf

FERCAP Newsletter

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