Forum for Ethical Review Committees in Asia and the Western Pacific

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FERCAP AT A GLANCE

Sixteen Asian Ethics Committees Recognized in 2008

Sixteen new Ethics Committees will be recognized during the FERCAP General Assembly on November 26, 2008 during the International Conference with the theme 'Empowering Stakeholders in Health Research: Towards Developing an Ethics of Accountability and Responsibility' held at Rama Garden Hotel in Bangkok.

The 16 Ethics Committees are as follows: **China:** Fudan University Huashan Hospital IRB; **Korea**: 1.Hallym Sacred Heart Hospital IRB; 2. Daegu Medical Center IRB; 3. Kyung Hee University Hospital IRB; 4. Ajou University Hospital IRB; **Taiwan:** 1. Cathay General Hospital IRB; 2. Taipei Medical University Wanfang Municipal Hospital IRB; 3. Buddhist Tzu Chi General Hospital IRB; 4. Kaohsiung Veterans General Hospital IRB; 5. Mackay Memorial Hospital IRB; **Thailand:** 1. Faculty of Tropical Medicine EC, Mahidol University; 2. Joint Research Ethics Committee; 3. Faculty of Medicine REC, Chiangmai University; 4. Research Institute for Health Sciences HEC, Chiangmai University; 5. Khon Kaen University EC; 6. Health Science Group ERC, Chulalongkorn University.

The Joint IRB of Taiwan will have its recognition renewed while the Republic of Tatarstan Regional Ethics Committee in Russsia will also get SIDCER Recognition.

Six Thai Ethics Committees Undergo SIDCER Survey in July

In July 20th through 30th, FERCAP organized SIDCER survey to six Ethics Committees in Thailand. This ten days survey was conducted with Prof. Juntra Karbwang as the overall coordinator, Dr. Ong-arj Viputsiri was the WHO-SEARO Resource Person, Prof. Cristina E Torres was FERCAP training coordinator, and Associate Prof. Sopit Thamaree worked as the local coordinator.

Six surveyors were divided into two teams, team A consists of Prof. Marita Reyes from Philippines, Dr. Xiuqin Wang from China and Dr. Paul Kumaran from India, this team surveyed Ethics Committee of Faculty of Tropical Medicine, Mahidol University; the Human Experimentation Committee, Research Institute for Health Science, Chiang Mai University; and Khon Kaen University Ethics Committee for Human Research. Team B consists of Dr. Heidi Liu from FERCAP, Professor Chih-Shung Wong and Dr. Chih-Han Lin from Taiwan, China, this team surveyed Joint Research Ethics Committee; Research Ethics Committee, Faculty of Medicine, Chiang Mai University; and The Ethical Review Committee for Research Involving Human Research Subjects, Health Science Group, Chulalongkorn University.

More Ethics Committees in Thai applying for SIDCER survey indicates that Ethics Committees in Thailand are pursuing for better quality in protecting human participants.

Thai Rural house: http://photos.igougo.com/pictures-l533-Chiang_Mai_photos.html

Chinese Fudan Huashan-IRB Welcomed SIDCER Survey Team in August

On Aug 28-31 2008, Institutional Review Board of Shanghai Huashan Hospital (HIRB), Fudan University, welcomed the SIDCER survey team which was composed of Prof. Sopit Thamaree from Thailand, Dr. Vicente Belizario from

Philippine and Dr. Benjamin Kuo from Taiwan, China, Prof. Cristina E. Torres and FERCAP Medical Officer Dr. Heidi Liu were acted as the overall coordinator for this survey. While highly admiring the general practice of HIRB, the survey team also provided recommendations for the improvement. HIRB deems the SIDCER Recognition the first step to achieve its missions to conduct efficient and high quality ethical and scientific review.

Huashan Hospital is the first Research Ethics and Good Clinical Practice (GCP) training center in China in collaboration with WHO/TDR. On Aug 27, 2008, with the representatives from other WHO/TDR training centers in Chulalongkorn University, Thailand, University of Manila, Philippine, Addis Ababa University and Ethiopian Science & Technology Agency, the coordinating meeting of the training centers was held in Huashan Hospital, whose objective is to harmonize and to standardize the training courses. Dr. Reijo Salmela, Medical Officer from WHO Western Pacific Regional Office participated the meeting.

Survey team in Shanghai HIRB, August 2008

INFORMATION SHARING

WHO Endorses Strategies to Stimulate Drug Development, Research into Diseases Afflicting Developing World

http://www.reuters.com/article/healthNews/idUSL2419043220080524

http://www.ft.com/cms/s/ad0950a6-2abc-11dd-b40b-000077b07658,Authorised=false.html?_i_location=http%3A%2F%2Fwww.ft.com%2Fcms%2Fs%2F0%2Fad0950a6-2abc-11dd-b40b-000077b07658.html%3Fnclick_check%3D1&_i_referer=&nclick_check=1

Reuters (5/25, MacInnis) reported that the "World Health Organization's (WHO) member governments overcame a rich-poor rift over how to manage intellectual property on Saturday, and endorsed a strategy to help developing countries access more life-saving medicines." A "hard-fought consensus reached by the 190 countries represented in the Geneva talks" also resulted in health authorities calling for the WHO "to finalize a plan of action boosting incentives for drug makers to tackle diseases that mainly afflict the poor."

Some action plans "could include prize funds to reward drug development, advance commitments to buy new drugs, or vaccines and patent pooling, where patent holders share technology to provide a common platform for further innovation," the Financial Times (5/26, Williams) added. But "the U.S. and other developed countries successfully fought off attempts by developing countries, led by Brazil, to weaken international rules on patent protection."

Clinical Trials in India: Ethical Concerns

http://www.who.int/bulletin/volumes/86/8/08-010808/en/index.html

According to the Associated Chambers of Commerce and Industry, an influential national industry association, India is set to grab clinical trials business valued at approximately US$ 1 billion by 2010, up from US$ 200 million last year, making the sub-continent one of the world's preferred destinations for clinical trials.

Drug companies are drawn to India for several reasons, including a technically competent workforce patient availability, low costs and a friendly drug-control system. While good news for India's economy, the booming clinical trial industry is raising concerns because of a lack of regulation of private trials and the uneven application of requirements for informed consent and proper ethics review.

Gulhati is particularly concerned about ethics committees lacking independence. "Fewer than 40 Ethics Committees in India are properly constituted and functioning, which means that the safety of the subjects of clinical trials is on the back burner," he says, adding that it is also worrying that there is no legal requirement for investigators or members of the Ethics Committees to declare a conflict of interest. He considers this a particularly serious problem given the increasing number of hospitals now owned by drug companies. "Clinical trials at such hospitals should carry a statement of disclosure about the relationship," Gulhati says.