



National Research Council  
of Thailand



Faculty of Medicine  
Chulalongkorn University



Thailand Convention &  
Exhibition Bureau



Chula Global Network



The Thai Red Cross  
Society

## The 16<sup>th</sup> FERCAP International Conference

### *Advancing Best Practices in Research Ethics across Asia and the Western Pacific*



**SIDCER**  
Globalizing Ethics for Health Research

Forum for Ethical Review Committees in Asia & the Western Pacific  
Strategic Initiative for Developing Capacity in Ethical Review

**VENUE: BhumiSiriManglanusorn 12th floor Building, King Chulalongkorn Memorial Hospital  
November 20-23, 2016**

**Address: 1873 Ratchadamri Rd, Pathum Wan, Bangkok 10330**  
อาคาร ภุมิสิริมังคลานุสรณ์ ชั้น 12 โรงพยาบาลจุฬาลงกรณ์ สภากาชาดไทย  
1873 ถนนพระรามที่ 4 แขวงปทุมวัน เขตปทุมวัน กรุงเทพฯ 10330

## Activity description

<b>FERCAP Pre-conference Program</b> November 20, 2016 FERCAP Pre-Conference Training, FERCAP Steering Committee Meeting (Room C)	
10.00 – 13.00	Middleton Foundation Activity (by Invitation)
13:00 – 13:30	<b>FERCAP Pre-conference Training: Best practices for EC/IRB chairpersons</b> Speaker: Cristina E. Torres
13:30 – 14:00	<b>IRB panel A</b> Role Play: Aphornpirom Ketupanya, Phramongkutklao College of Medicine Thipaporn Tharavanij, Faculty of Medicine, Thammasat University Mano Laohavanich, Chulabhorn International College of Medicine, Thammasat University
14:00 – 15:00	Open discussion
15:00 – 15:30	Break
15:30 – 16:00	<b>IRB panel B</b> Role Play: Unnop Jaisamrarn, Faculty of Medicine, Chulalongkorn University Rattana Kumwilaisuk, Faculty of Medicine, KhonKaen University Tada Sueblinvong, Faculty of Medicine, Chulalongkorn University
16:00 – 17:00	Open discussion
17:00 – 18:00	Wrap Up Speaker: Cristina E. Torres
18:00 – 21:00	FERCAP Steering Committee Meeting

# FERCAP Conference: Day 1 Program

November 21, 2016

9:00 – 19:30

9:00 – 9:30 (Rooms A, B, C, D) 12th Floor	<b>Opening Ceremony</b>
	<p><b>- Welcome Speech</b> Kenji Hirayama, FERCAP Chairman</p> <p><b>- Opening Remarks</b> Piyasakol Sakolsatayadorn Minister of Public Health</p> <p><b>Keynote Address: The contribution of best practices in research ethics to a harmonized approach toward health research across Asia</b> Piyasakol Sakolsatayadorn Minister of Public Health</p>
9.30 – 9.45	<b>Inspirational Address: A tribute to Dr. Angela J. Bowen</b>
	<p><b>Achieving best practices through thirteen years of the Middleton Foundation International Fellows Program</b> Speaker: Chaichana Nimnuan Faculty of Medicine, Chulalongkorn University</p>
9:45 – 10:00	Tea/Coffee break
10:00 – 11:00 (Rooms A, B, C, D) 12th Floor	<b>National Policies: The contribution of research ethics regulation to best practices in health research in Asian countries</b>
	<p>Session Chair: Aphornpirom Ketupanya Co-Chair: Vicente Belizario Jr.</p> <p>Speaker: Tsang-Tang Hsieh Chair of Taiwan Association of Institutional Review Boards</p> <p>Speaker: Cristina E. Torres Social Science Professor, University of the Philippines Manila</p> <p>Speaker: Sopit Thamaree Consultant of National Ethics Committee Accreditation System of Thailand</p>
11:00 – 11:30	<b>Open discussion</b>
	Rapporteur: Francis P. Crawley
11:30 – 12:15 (Room A,B,C,D) 12th Floor	<b>Best practices in the ethics of traditional medicine and integrative medicine research</b>
	<p>Session Chair: Vichai Chokvivat Co-Chair: Kian Meng Chang</p> <p>Speaker: Anchalee Chutaputti Department for the Development of Thai Traditional and Alternative Medicine</p> <p>Speaker: Vasantha Muthuswamy President of The Forum for Ethics Review Committees of India</p> <p>Speaker: Cecilia C. Maramba-Lazarte Director, Institute of Herbal Medicine, National Institutes of Health, UP Manila</p>
12:15 – 12:45	<b>Open discussion</b>
	Rapporteur: TBC
12:45 – 13:45	Lunch break

Parallel session and Poster viewing				
13:45 – 14:30 (Rooms A, B, C, D) 12th Floor	<b>Thai-language session</b>	<b>Specialized topic papers</b>		
	<b>Best practices in the ethics of research in the social and behavioral sciences (Room D)</b>	<b>Best practices in the social and behavioral sciences (Room A)</b>	<b>Best practices in traditional and integrative medicines(Room B)</b>	<b>Best practices in the informed consent process (Room C)</b>
	Moderator: Santhat Sermsri  Speaker: Sivalee Sirilai The Royal Society of Thailand  Speaker: Supaporn Sudnongbua Faculty of Public Health, Naresuan University	Session Chair: Preeda Tasanapradit  <b>Speaker:</b>  Grace Aguling Dalisay, <i>Reviewing psychology protocols</i>  Vicente Belizario Jr., <i>Conducting community-based research in public health</i>  Xueqin Wang, <i>Consenting Psychiatric Patients</i>	Session Chair: Vasantha Muthuswamy <i>Ethics review of traditional medicine</i>  <b>Speaker:</b>  Korea: Im Hee Shin  Indonesia: Eti Nurwening Sholikhah  Thailand: Krit Pongpirul et al.	Session Chair: Kwanchanok Yimtae  <b>Speaker:</b>  Nut Koonrungsom boon et al, <i>Developing an enhanced informed consent form</i>  Thipaporn Tharavanij et al., <i>Improved understanding of research information</i>  KSP Gan, KM Chang et al, <i>GCP Compliant Information Sheet</i>
14:30-15:00	<b>Open discussion</b>	<b>Open discussion</b>	<b>Open discussion</b>	<b>Open discussion</b>
	Rapporteur: Jaggapan Cadchumsang	Rapporteur: Napakawat Buathong	Rapporteur: Nuttawut Saelim	Rapporteur: Prapapan Rajatapiti
15:00 – 15:30	Tea/Coffee break			
15.30 – 16:00 (Rooms A, D) 12th Floor	<b>Best practices in the ethics of first-in-human clinical trials(Room A)</b>		<b>Best practices in the ethics of the social and behavioral sciences (Room D)</b>	
	Session Chair: Juntra Karbwang Co-Chair: Thipaporn Tharavanij  Speaker: Francis P. Crawley Good Clinical Practice Alliance – Europe  Speaker: Kian Meng Chang Chair Malaysian Ministry of Health Research Ethics Committee		Session Chair: Cristina E. Torres Co-Chair: Jaggapan Cadchumsang  Speaker: Akiko Matsuyama Nagasaki University  Speaker: Thapin Phatcharanuruk, Faculty of Social Sciences, Chiang Mai University	
16:00-16:30	<b>Open discussion</b>		<b>Open discussion</b>	
	Rapporteur: Nut Koonrungsomboon		Rapporteur: Napakawat Buathong	
16:30 – 17:30	Meeting of the Conference Rapporteurs: Francis P. Crawley and Rapporteurs			
17:30 – 19:30	Welcome Dinner			

# FERCAP Conference: Day 2 Program

November 22, 2016

9:00 – 16:30

9:00 – 10:00 (Rooms A, B, C, D) 12th Floor	<b>Regulatory requirements for investigational medical device:</b> <i>Classification of medical device</i> <i>Clinical data supporting medical device registration</i>			
	Session Chair: Tsang-Tang Hsieh Moderator: Pravich Tanyasittisuntorn  Speaker: David Forster Western Institutional Review Board (WIRB)  Speaker: Suhoung Thitisatthayakorn Senior Expert on Medical Device Safety			
10:00 – 10:30	<b>Open discussion</b>			
	Rapporteurs: Somruedee Chatsiricharoenkul, Utcharee Intusoma			
10:30 – 10:45	Tea/Coffee break			
10:45 – 11:30 (Rooms A, B, C, D) 12th Floor	<b>Best practices in the writing and review of medical device protocols</b>			
	Session Chair: Kenji Hirayama Moderator: Kwanchanok Yimtae  Speaker: Surasith Piyasin Faculty of Engineering, Khon Kaen University  Speaker: Hiroshi Yamamoto Director of Clinical Research Center, Nagasaki University Hospital			
11:30 – 12:00	<b>Open discussion</b>			
	Rapporteurs: Somruedee Chatsiricharoenkul, Utcharee Intusoma			
12:00 – 13:00	Lunch break			
13:00 – 14:30 (Rooms A, B, C, D) 12th Floor	<b>Thai-language session (Room D)</b>	<b>Specialized topic papers (Rooms A, B, C)</b>		
	<b>Best practices of EC/IRB chairpersons and secretaries (Room D)</b>	<b>Promoting best practices in the ethics of clinical research (Room A)</b>	<b>Quality control and quality assurance in research ethics (Room B)</b>	<b>Promoting best practices among research ethics committees in Asia-Pacific (Room C)</b>
	Speaker: Tada Sueblinvong Faculty of Medicine, Chulalongkorn University  Speaker: Rattana Kumwilaisuk Faculty of Medicine, Khon Kaen University	Session Chair: Deok Soo Kim  <b>Speaker:</b> Rosemarie D.L.C. Bernabe, <i>Ethical issues in Phase 4 studies</i>  Hemantha Senanayake, <i>Ethical Issues in Obstetrics and Gynecology Research</i>  Cao Cai, <i>Proposed cooperation of China GCP Union with FERCAP</i>  Patricia Khu, <i>Assessment of Protocol Deviation in Clinical Trials.</i>	Session Chair: Magdarina Destri Agtini  <b>Speaker:</b> Chairat Shayakul et al., <i>Timelines for IRB approval</i>  Gurpreet Kaur et al., <i>Learn management strategy for expedited review</i>  Bailu Wang, <i>China FDA inspection of Clinical Trial</i>	Session Chair: Qi Lu  <b>Speaker:</b> Ian Tindall, <i>Ethical conduct in human research: The view from the Chair</i>  Sumalee Kondo et al., <i>Efficient performance of IRBs</i>  Suryani As'ad et al., <i>Role of IRB in JCI Accreditation</i>
14:30-15:00	<b>Open discussion</b>	<b>Open discussion</b>	<b>Open discussion</b>	<b>Open discussion</b>
	Rapporteur: Ariyabhorn Kuroda	Rapporteur: Surapoj Meknavin	Rapporteur: Supattra Porasuphatana	Rapporteur: Pantipa Wongwai
15:00 – 15:30	Tea/Coffee break			

15:30 – 16:30 (Rooms A, B, C, D) 12th Floor	<p style="text-align: center;"><b>Closing Session</b></p> <p>Session Chair: Juntra Karbwang</p> <p><b>Harmonizing Best Practices Globally: Risk-based quality management in clinical trials and the role of the ethics committee/IRB</b></p> <p>Speaker: Francis P. Crawley Good Clinical Practice Alliance – Europe</p>
16:30-17:00	<b>Open discussion</b>
	Rapporteur: TBC

17:00 – 18:00	Meeting of the Conference Rapporteurs: Francis P. Crawley and Rapporteurs
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<p><b>FERCAP Conference: Day 3 Program</b></p> <p>November 23, 2016</p> <p>9:00 – 12:00</p>	
9:00 – 9.30 (Room A) 12th Floor	<p style="text-align: center;"><b>Conference Rapporteurs Report</b></p> <p style="text-align: center;">Asian best practices in health research ethics and ethical review: <b>Harmonizing standards while respecting differences in national and cultural approaches</b></p> <p>Speaker: Francis P. Crawley</p>
09.30 – 10.15 (Room A) 12th Floor	<p style="text-align: center;"><b>FERCAP Networking Activity</b></p> <p>Moderator: Arthur Navarro</p>
10:15 – 12:30 (Room A) 12th Floor	<b>FERCAP General Assembly and Recognition Ceremony</b>
12:30	Farewell time