

Pre-conference - 16 September 2010		
0900 - 1800	Concurrent Sessions (Agenda to be available soon)	
	Institutional Review Board (IRB) 101sm	
	Instructors	
	Session Description	
	Mr David Borasky, MPH, CIP, (United States)	Institutional Review Board (IRB) 101sm is a full-day programme that will feature a series of lectures, interactive discussions, and case studies. The two experienced PRIM&R faculty members leading this course will review:
	Ms Helen McGough, MA, CIP, (United States)	<ul style="list-style-type: none"> • The development of the Institutional Review Board (IRB) / ethics review systems • The underlying ethical principles and procedures for reviewing research involving the protection of human subjects; and • The key components of principles and regulations that govern Institutional Review Board (IRB) / Ethics Committee (EC) operations
	Institutional Review Board (IRB) 201	
	Instructors	Session Description
	Dr Jeffrey A. Cooper, MD, MMM (United States)	Institutional Review Board (IRB) 201 is designed to provide the knowledge needed to become experienced Institutional Review Board (IRB) / ethics committee (EC) chairs, members, and staff. This educational program will include information directly relevant to IRB / EC chairs, members, and staff who conduct reviews as part of a convened IRB / EC or through the expedited procedure. This course has been designed for IRB / EC members and staff who understand the fundamentals of IRB / EC operations and who are now interested in obtaining the next level of training.
	Ms Elizabeth Bankert, MA, (United States)	<p>By attending Institutional Review Board (IRB) 201, participants will gain the knowledge and skills needed both to serve as effective IRB / EC reviewers and to teach others to become effective IRB / EC reviewers. Note that this course will not cover administrative issues of IRB / EC operations.</p> <p>The highly regarded faculty members leading this course will highlight key criteria for the review of research, including:</p> <ul style="list-style-type: none"> • Risks to participants are minimized; • Risks are reasonable in relation to anticipated benefits; • Selection is equitable; • Informed consent will be sought and waivers of informed consent; • Informed consent will be documented including waivers of documentation; • Research plan makes adequate provisions for monitoring safety; • Adequate provisions to protect privacy and maintain confidentiality; and • Additional safeguards for participants likely to be vulnerable to coercion or undue influence.

Day 1 - 17 September 2010		
0900 - 1000	Opening and Keynote Opening Address: Professor Edison Liu, Singapore Chairman, Health Sciences Authority (HSA), Singapore Keynote Speaker: Professor Alexander Capron, United States Professor of Law and Medicine, University of Southern California Co-Director of the Pacific Center for Health Policy and Ethics President of the International Association of Bioethics	
1000 - 1020	Tea break	
1020 - 1100	Plenary 1	
1100 - 1230	Concurrent Sessions	
	Session A1: IRB Framework and Operations	
	Speakers	Designation & Institution
	Dr Khalid Abdulla Alali (Qatar)	Shafallah Medical Genetic Center, Qatar University, Qatar
	Dr Lee Suk Koo (Korea)	President, Korean Association of IRB (KAIRB), Korea
		Topic
		Starting an Effective IRB Framework
		Korean Experiences of IRB Association to meet Global Standard
	Session A2: Study Start-Up	
	Speakers	Designation & Institution
	Dr Mohammadreza Ghandforoosh Sattari (Iran)	Tabriz University, Iran
	Prof Yong Eu Leong (Singapore)	Chief Obstetrics & Gynaecology, Vice-Chairman (Research) Medical Board, National University of Health Systems, Singapore
		Topic
		Ethics and Pharmaceutical Industry
		Responsible and Ethical Grant Stewardship
	Session A3: ASEAN Update	
	Speakers	Designation & Institution
	Mr Foo Yang Tong (Singapore)	Acting Director, Clinical Trials Branch, Health Products Regulation Group, Health Sciences Authority, Singapore
	Dr Che Ngah Anisah (Malaysia)	Lecturer, Faculty of Law, University Kebangsaan Malaysia, Malaysia
	Dr Nguyen Ngo Quang (Vietnam)	Secretary of IEC, Ministry of Health (MoH), Vietnam
		Topic
		Regulatory Update from Singapore
		Regulatory Update from Malaysia
		Regulatory Update from Vietnam
	Session A4: Informed Consent	
	Dr Zhu Wei (China)	Member of Centre for Applied Ethics, Fudan University of Shanghai, China
	Mr Chan Tuck Wai (Singapore)	Associate Director, National University of Singapore IRB, Singapore
		Topic
		Informed Consent and Impact of Chinese Culture on Informed Consent
		Consent for Donating Leftover Tissues in Singapore
1230 - 1400	Networking Lunch	
1400 - 1500	Panel Discussion	

1500 - 1630	Concurrent Sessions		
	Session B1: Self-Assessment and Accreditation		
	Speakers	Designation & Institution	Topic
	Ms Yerii Lee (Korea)	IRB Member, Samsung Biomedical Research Institute, Korea	How Accreditation can Change Human Research Protection Programmes
	A/Prof Chin Jing Jih (Singapore)	REC Chairperson, Tan Tock Seng Hospital, Singapore	Accreditation: How to Prepare and What to Expect
	Session B2: Patient Recruitment & Management		
	Speakers	Designation & Institution	Topic
	Dr Subramaniam Tavintharan (Singapore)	Senior Consultant, Alexandra Hospital, Singapore	Ethical Issues and Challenges in Patient Recruitment
	Dr Ihnsook Jeong (Korea)	Assistant Professor, Pusan National University, Korea	Quality of Obtaining Informed Consent for Healthy Volunteer
	Session B3: East Asia Update		
	Speakers	Designation & Institution	Topic
	Dr Toshi Tominaga (Japan)	Director, Office for International Program, PMDA, Japan	Regulatory Update from Japan
	Prof Ock-Joo Kim (Korea)	Associate Professor, College of Medicine, Seoul National University, Korea	Regulatory Update from Korea
	Session B4: Vulnerable Populations		
	Dr Merle Spriggs (Australia)	Honorary Fellow, Human Research Ethics Committees, Children's Bioethics Centre, Australia	Special Considerations in Studies Involving Children
A/Prof Sandra Egger (Australia)	Chair, Justice Health HREC, Australia	Special Considerations in Studies Involving Prisoners	
Session B5: International Research Capacity Building			
Dr Athula Sumathipala (Sri Lanka)	Senior Lecturer, Department of Epidemiology, Institute of Psychiatry, Sri Lanka	To be advised	
Dr Mohanish Anand (India)	Regional Head Clinical Operations-Asia, Pfizer Global Research & Development, India	To be advised	
1630 - 1650	Tea break		
1650 - 1750	Concurrent Sessions		
	Session C2: Managing & Maintaining Quality		
	Speakers	Designation & Institution	Topic
	Ms Rucha Majmundar Mehta (India)	RQ Consulting, India	GCP Application
	Session C3: Southern Asia Update		
	Speakers	Designation & Institution	Topic
Dr Farha Nasreen Rizwan Sikalgar (India)	Secretary Ethics Committee, M.C.E.Society and MMERC, Pune, Maharashtra, India	Regulatory Update from India	
1800 - 1900	Poster Presentation / Free Viewing		

Day 2 – 18 September 2010		
0900 - 1000	Plenary 2	
1000 - 1020	Tea break	
1020 - 1100	Plenary 3	
1100 - 1230	Concurrent Sessions	
Session D1: Essentials Concepts and Skills for Community/ Non-scientists IRB Members		
Speakers	Designation & Institution	Topic
Dr Allan Harkness (Singapore)	Research Ethics Committee Advisor, AGST Alliance, Singapore	What Does it Mean to Represent the Community?
Dr Yap Von Bing (Singapore)	Assistant Professor , Statistics and Applied Probability, National University of Singapore	Understanding Common Study Designs and Vocabulary of Statistics in Protocol Review
Session D2: Ethical & Responsible Conduct of Research		
Speakers	Designation & Institution	Topic
Dr Michael G. Irwin (Hong Kong)	Head, Department of Anaesthesiology, The University of Hong Kong, Hong Kong	The Perfect Investigator
Prof Abhik Gupta (India)	Professor , Department of Ecology & Environmental Science, Assam University, India	Flu Pandemic Threat: Ethical Issues
Session D3: Middle East Update		
Speakers	Designation & Institution	Topic
Prof Saleh A. Bawazir (Saudi Arabia)	Vice President for Drugs Affairs, Saudi Food and Drug Authority, Saudi Arabia	Role of Saudi Food and Drug Authority in Regulating Clinical Trials
Dr Abdulmohsen Alrohaimi (Saudi Arabia),	Head, Research Department, Saudi Food and Drug Authority, Saudi Arabia	Regulatory Update of Saudi Arabia
Dr Al-Hareth M. Al- Khater (Qatar)	Assistant Chairman, Dept. of Hematology & Oncology, Chairman, Al Amal Hospital Medical Research Centre, Hamad Medical Corporation, Qatar	Regulatory Update from Qatar
1230 - 1330	Lunch	
1330 - 1500	Concurrent Sessions	
Session E2: Training and Education for the Site Staffs and Clinical Research Professionals (CRP)		
Speakers	Designation & Institution	Topic
Dr Joe Badolato (Australia)	ARCS Australia Ltd, Australia	Educating Study Site Staff on GCP Compliance
Dr James Fan (Singapore)	Associate Director, ICON Clinical Research Pte Ltd, Singapore	Role of medical monitor that ensures FDA and GCP compliance
Session E3: US Federal Regulations		
Speakers	Designation & Institution	Topic
Dr Robert Nelson (United States)	Pediatric Ethicist, Office of Pediatric Therapeutics, US FDA	The Scientific and Ethical Pathway for Developing Pediatric Therapeutics

Session E4: Ethical Issues and Challenges in Phase I Research

Speakers	Designation & Institution	Topic
Dr Winston Liauw (Australia)	Chairman, St George Hospital Ethics Committee , Australia	Strategies for Helping Your IRB Review Phase I Clinical Trials Ethically and Efficiently
Dr Danny Soon, (Singapore)	Managing Director, Lilly-NUS Centre for Clinical Pharmacology, Singapore	Challenges in Phase I Trial

Session E5: Conducting Research in Low and Medium Resource Countries

Speakers	Designation & Institution	Topic
Prof Leonardo D. De Castro (Singapore)	Editor-in-Chief Asian Bioethics, National University of Singapore (NUS) , Singapore	International Issues in Research
Dr Athula Sumathipala (Sri Lanka)	Senior Lecturer, Department of Epidemiology, Institute of Psychiatry, Sri Lanka	To be advised

1500 - 1600
Concurrent Sessions
Session F1: IRB Reciprocity Agreement

Speakers	Designation & Institution	Topic
Dr Lisa Leiden (United State)	Associate Vice Chancellor, The University of Texas System, USA	IRB Reciprocity Agreement

Session F2: Legal Requirements of the Sponsors in Protecting Human Research Participants

Speakers	Designation & Institution	Topic
Ms Ling Ho (Hong Kong)	Partner, Litigation and Dispute Resolution, Asia, Clifford Chance Hong Kong	To be advised
Ms Kuah Boon Theng (Singapore)	Director, Legal Clinic LLC, Singapore	To be advised

Session F3: Pharmaceutical Company's Perspective on Drug Development and interactions with regulatory agencies in Asia

Speakers	Designation & Institution	Topic
Dr Mohanish Anand (India)	Regional Head Clinical Operations- Asia, Pfizer Global Research & Development, India	To be advised

Session F4: Genetic Research

Speakers	Designation & Institution	Topic
Dr Eva Maria Cutiongco-de la Paz (Philippines),	Director - Institute of Human Genetics, National Institute of Health Philippines, Philippines	Ethical Issues in Genetic Research in a Developing Country

Session F5: International Trial Design Issues and Outsourcing

Speakers	Speakers	Speakers
Prof Martin Mao- Tsu Fuh (Taiwan)	Chair, Institutional Review Board, China Medical University Hospital, Taiwan	The Post-Trial Human Protection – Based on the tangible tracking mechanism

1600 - 1620	Tea break		
1620 - 1750	Concurrent Sessions		
	Session G1: (G1) Challenges Facing Ethics Review Board in Detecting and Managing Adverse Events in Clinical Researches		
	Speakers	Designation & Institution	Topic
	Prof Jody Dalmacion (Philippines)	Professor, University of the Philippines, Philippines	Role of Ethics Review Board in Adverse Drug Event Reporting
	Session G4: (G4) Research on Traditional Medicine		
Speakers	Designation & Institution	Topic	
Dr Jacinto V. Mantaring III (Philippines)	Associate Professor of Clinical Epidemiology, Philippines	Philippines Ethics Guidelines for Research on Traditional and Herbal Medicine	

These following speakers will also be speaking at APREC 2010. Their specific tracks and sessions will be updated soon.

- 1) Dr Balein Gemma, Philippine
- 2) Dr Benny Chung-Ying Zee, Hong Kong
- 2) Dr Chiang Shu-Chiung, Taiwan
- 3) Dr Farooqui Arshi, Pakista
- 4) Prof Harun-Ar-Rashid, India
- 6) Dr Jaime Montoya, Philippine
- 7) Dr Jeremiah Kenner, Australia
- 8) Dr Jugal Kishore , India
- 9) Dr K. Srinivasan, India
- 11) Dr Meghachandra Singh , India
- 12) Prof Michael Cheng-tek Tai, Taiwan
- 13) Dr Nalin Mehta, India
- 14) Dr Nandini K Kumar, India
- 16) A/Prof Sara R. Jordan, Hong Kong
- 17) Dr Tsang-Tang Hsieh, Taiwan
- 18) Dr V.K. Gupta, India
- 19) Dr V. Mohanan Nair, India

NOTE

- **Scientific programme is accurate at the time of update. Details are subject to changes.**
- **For the latest Conference program, please check our website at www.aprec-nhg.com.sg**