



18th FERCAP ANNUAL CONFERENCE and

Taiwan-China Cross Straits Forum on Research Ethics

November 18-21, 2018

CHANG GUNG MEMORIAL HOSPITAL

Taoyuan, Taiwan

**Theme: Strengthening Scientific Innovation and Ethical
Assessment of Health Research**

Conference Schedule

18 November 2018 Sunday (13:00-17:00)	Pre-Conference Training: Ethics Review of Innovative Design
19-20 November 2018 Monday-Tuesday	Conference Proper
21 November 2018 Wednesday	FERCAP Recognition Program and General Assembly

Conference Objectives

- To highlight current trends and innovative approaches in health research
- To discuss the challenges in ethics review of innovative designs in health research
- To describe the role of research ethics committees in promoting good science and ethics in health research
- To describe the roles of various stakeholders in promoting good research ethics practices within the context of innovation and globalization
- To discuss the ethical assessment of big data health researches
- To provide a venue for cross straits discussion of scientific innovation and ethics



Conference Registration:

For Foreign Participants

E-mail: atoynavarro@yahoo.com

For Local Participants

Contact: TAIRB

tairb.2009@gmail.com

Onsite Registration: 13:00-17:00, 18 November 2018; 08:00-12:00, 19 November 2018 -

Poster Presentations: 18-21 November 2018

By Research Ethics Committees and Researchers

FERCAP Pre-Conference Workshop:

13:00-17:00, 18 November 2018

Linkou Changgung Memorial Hospital, Taoyuan, Taiwan

Resource Persons: Facilitators from the Global Forum for Bioethics in Health Research

Participants: REC members and investigators

Training on ethical issues of innovative alternative designs in health research

- Step Wedged Cluster Randomized Trial (SWCRT)
- Adaptive Platform Trial
- Use of Controlled Human Infection Models

Objectives:

- To discuss case studies that make use of innovative/alternative designs in health research
- To discuss the ethical issues in innovative designs
- To support participants from LMICs to participate in the workshop
- To develop common approaches in the review of innovative design in health research in Asia-Pacific

AGENDA

13:00-13:30	Introduction to the Use of Novel/Alternative Design in Health Research
13:30-14:00	Case study 1: Use of Step Wedged Cluster Randomized Trial
14:00-14:30	Case study 2: Adaptive Platform Trial
14:30-15:00	Case study 3: Use of Controlled Human Infection Models
15:00-16:00	Group Discussions
16:00-17:00	Group Reports
17:00-17:30	Synthesis

FERCAP Steering Committee Meeting: 18:00-21:00, 18 November 2018

Welcome Dinner and Cultural Program: 15:00-21:00, 19 November 2018

Conference Proper: 08:30-17:00, 19-20 November 2018

FERCAP Recognition Ceremony: 09:00-12:30, 21 November 2017



Conference Agenda									
Day 1: 19 November 2018									
08:00-08:45	Opening Ceremony								
	<table border="1"> <tr> <td>Session Chairs:</td> <td> Kenji Hirayama FERCAP Chair Tang Tsang Hsieh TAIRB Honorary President </td> </tr> <tr> <td>Welcome Address</td> <td></td> </tr> <tr> <td>Introduction of Guests/Delegation</td> <td></td> </tr> <tr> <td> KEYNOTE Speech Taiwan Experience in Scientific Innovation and Ethics in Biomedicine </td> <td> Hsueh Jui-Yuan Deputy Minister, Taiwan Ministry of Health and Welfare </td> </tr> </table>	Session Chairs:	Kenji Hirayama FERCAP Chair Tang Tsang Hsieh TAIRB Honorary President	Welcome Address		Introduction of Guests/Delegation		KEYNOTE Speech Taiwan Experience in Scientific Innovation and Ethics in Biomedicine	Hsueh Jui-Yuan Deputy Minister, Taiwan Ministry of Health and Welfare
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	Welcome Address								
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KEYNOTE Speech Taiwan Experience in Scientific Innovation and Ethics in Biomedicine	Hsueh Jui-Yuan Deputy Minister, Taiwan Ministry of Health and Welfare								
08:45-10:00 Session 1	Update in National/International Guidelines								
	<table border="1"> <tr> <td>Session Chairs:</td> <td> Fu Chang Tsai TAIRB President Vicente Belizario Vice Chair, FERCAP </td> </tr> <tr> <td> Declaration of Taipei 2016 Highlights of CIOMS 2017 Implications of Revisions of International Guidelines to Ethics Review </td> <td> Fu-Chang Tsai TAIRB President National Taiwan University </td> </tr> </table>	Session Chairs:	Fu Chang Tsai TAIRB President Vicente Belizario Vice Chair, FERCAP	Declaration of Taipei 2016 Highlights of CIOMS 2017 Implications of Revisions of International Guidelines to Ethics Review	Fu-Chang Tsai TAIRB President National Taiwan University				
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Declaration of Taipei 2016 Highlights of CIOMS 2017 Implications of Revisions of International Guidelines to Ethics Review	Fu-Chang Tsai TAIRB President National Taiwan University								
10:00-10:30	Coffee/Tea Break								
10:30-12:00 Session 2	Promoting Good Practice in Science and Ethics								
	<table border="1"> <tr> <td>Session Chairs:</td> <td> Chih Shung Wong Cathay General Hospital </td> </tr> <tr> <td> Ethical Issues in Biobanks and Personalized Medicine Setting Up a Public Health Practice Ethics Committee </td> <td> Kenji Hirayama FERCAP Chair Jacinto Blas Mantaring III University of the Philippines </td> </tr> </table>	Session Chairs:	Chih Shung Wong Cathay General Hospital	Ethical Issues in Biobanks and Personalized Medicine Setting Up a Public Health Practice Ethics Committee	Kenji Hirayama FERCAP Chair Jacinto Blas Mantaring III University of the Philippines				
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	<p>Use of Electronic Consent Forms for Better Participation</p> <p>Multi-country Perception about Information in the Informed Consent Form</p>	<p>IQVIA</p> <p>Juntra Laothavorn SIDCER Coordinator</p>	
12:00-13:00	Lunch Break and Poster Viewing		
13:00-14:30 Session 3	Parallel Sessions		
	Ethical Challenges in Clinical Research	Ethics Education/ Information in Research	Ethical Challenges In Ethics Review
	Venue 1	Venue 2	Venue 3
	Parallel Session 3A	Parallel Session 3B	Parallel Session 3C
	<p>Session Chair: Juntra Laothavorn SIDCER Coordinator</p>	<p>Session Chair: Vasantha Muthuswamy FERCAP Steering Committee (India)</p>	<p>Session Chair: Aphornpirom Ketupanya FERCAP Steering Committee (Thailand)</p>
	<ul style="list-style-type: none"> • Promoting Clinical Trial Collaboration in Integrative Medicine Im Hee Shin, Korea • Clinical Practice and Stem Cell Research Saturnino Javier Jr., Philippines • Using Infrapatellar Fat Pad Mesenchymal Stem Cells for Knee Osteoarthritis Treatment Chih-Hung Chang, Taiwan • Ethics: The ideal Behavior or Attitude? Chien-Hsing Wang, Taiwan 	<ul style="list-style-type: none"> • Developing a Diploma Program in Research Methods and Ethics in Myanmar Theingi Myint et al., Myanmar • Designing a Research Ethics Program for EC Members in Bangladesh Shamima Lasker & Saiful Islam, Bangladesh • Training in Protocol Writing to Avoid Delays in Protocol Review Sumalee Kondo et al., Thailand • Informing Participants about Research Sriwimon Manochiopinig et al., Thailand • Integrated Resources for Research Ethics 	<ul style="list-style-type: none"> • Reviewing Medical Device Protocols Korea • Setting Up a Subcommittee for Medical Device Protocols Phantipha Wongwai et al., Thailand • Post-Trial Provisions in Sponsored Initiated Trials Rosemarie Bernabe et al., Norway • Challenges in the Use of e-Software for EC Operations Yashashri Shetty et al., India



		Education in Taiwan: AREE Chien Chou, Taiwan	
14:30-15:00	Coffee/Tea Break		
15:00-21:00	Visit to the Palace Museum Welcome Dinner		

Day 2: 20 November 2018			
08:30-10:00 Session 4	Parallel Sessions		
	Conducting Research Among Vulnerable Populations	National Regulations and Ethics Review	Cross Straits Discussion on Research Ethics
	Venue 1	Venue 2	Venue 3
	Parallel Session 4A	Parallel Session 4B	Parallel Session 4C
	Session Chair: Cristina Torres FERCAP Coordinator	Session Chair: Magdalena Agtini FERCAP Steering Committee (Indonesia)	Session Chair: Tsang Tang Hsieh Changgung Memorial Hospital
	<ul style="list-style-type: none"> • Ethical Issues in Malnutrition Studies Suryani As'ad, Indonesia • Informed Consent among Disabled Subjects Abdus Shakoor, Bangladesh • Perception about Clinical Trials of Cancer Patients Cristina Torres, Philippines • Ethical Issues in HIV Trials Pearl Kosala Raman, India 	<ul style="list-style-type: none"> • Streamlining Research Ethics Review in the Health Sector Pio Justin Asuncion, Philippines • Regulatory Registration of ECs Tushar Nishandar et al., India • REC Compliance with Clinical Trial Act Yoichi Yamamoto, Japan • Salary Incentives for Good Research in Ministry of Health AKSB De Alwis et al., Sri Lanka 	<ul style="list-style-type: none"> • Central and Joint IRB Review in Taiwan I-Ning Tang, Taiwan • Approaches to Single IRB Review in China Qi Lu, Shanghai • Reviewing Non-Compliance/ Violation Reports Ni Shaoqing, Zhejiang • Issues about Informed Consent Form Kang-Ju Chou, Taiwan • Research Ethics in Robot Development Jhi-Joung Wang, Taiwan
10:00-10:30	Coffee/Tea Break		
10:30-12:00 Session 5	Parallel Sessions		
	Ethical Challenges in Continuing Review	Ethical Challenges in Innovative Research	Cross Straits Discussion on Clinical and Research



	Venue 1	Design	Ethics
	Venue 1	Venue 2	Venue 3
	Parallel Session 5A	Parallel Session 5B	Parallel Session 5C
	Session Chair: Deok Soo Kim FERCAP Steering Committee (Korea)	Session Chair: Jacinto Blas Mantaring III University of the Philippines	Session Chair: Qi Lu FERCAP Steering Committee (China)
	<ul style="list-style-type: none"> • Comparing Final Reports with Approved Versions of Protocols Snehalata Gajbhiye et al., India • Analysis of Safety Reporting in RCTs Mahanjit Konwar et al., India • Measuring Impact of Offsite SUSARs Prajakta Auti et al., India 	Panel Discussion <ul style="list-style-type: none"> • Human Infection Model • Adaptive Trial Design • Cluster Randomized Trial Design 	<ul style="list-style-type: none"> • Ethical Challenges in Traditional Chinese Medicine Wang Jing, Beijing • Ethical Issues in Bariatric and Metabolic Surgery Chih Yen Chen, Taiwan • An Ethical Exploration of Privacy and Genetic Information in the Age of Big Data Sihu Xu & Yue Tian, China • Using Site Visits to Improve the Quality of Clinical Trials Lee-Wei Chen, Taiwan
12:00-13:30	Lunch Break and Poster Viewing		
13:30-15:00	Capacity Building in Research Ethics		
Session 6	Single/Joint Review of Multicenter Research	Promoting Academic Research	Assessment of REC Performance
	Venue 1	Venue 2	Venue 3
	Parallel Session 6A	Parallel Session 6B	Parallel Session 6C
	Session Chair:	Session Chair:	Session Chair:
		Hans Amin Van Rostenberghe Universiti Sains Malaysia	Jiin Ger Taipei Veterans General Hospital
	Panel Discussion	<ul style="list-style-type: none"> • Defining the Role of Academic Advisers Philippines • Improving Academic Publication through Good REC Procedures 	<ul style="list-style-type: none"> • Factors Associated with Delayed REC Approval Thana Khawcharoenporn et al., Thailand
	<ul style="list-style-type: none"> • Common Ethics Review of Multicenter Research in India Rajib Kishore Hazam et al., India 		



	<ul style="list-style-type: none"> • Setting-up Single Joint Review in the Health Sector Michelle Barbara de Guzman, Philippines • Introducing Single Review System in Japan Yoichi Yamamoto, Japan • Central Ethics Review in MOH Malaysia • Central Research Ethics Committee in Thailand Aphornpirom Ketupanya, Thailand 	<p>Indonesia</p> <ul style="list-style-type: none"> • Compliance with Publication Ethics Junjira Laothavorn, Thailand 	<ul style="list-style-type: none"> • Performance Indicators after FERCAP Recognition Md Said Salmiah et al., Malaysia • Comparing International and Domestic Assessment Standards in Research Ethics in Korea Hyun Woo Kim, Korea
15:00-15:30	Coffee/Tea Break		
15:30-17:00 Session 7	Multiple Perspectives about Data Sharing		
	Session Chairs:	<p>Vajira Dissanayake FERCAP Steering Committee (Sri Lanka)</p> <p>Fung Wei Chang Tri-Service General Hospital, Taiwan</p>	
	<p>Ethical Issues in Using Health Databases</p> <p>Ethical Assessment of Big Data Health Research</p> <p>Equitable Data Sharing</p> <p>Ethics and Best Practices in Sharing Health Research Data</p>	<p>AS Aswamy Universiti Sains Malaysia</p> <p>Fung Wei Chang Tri Service General Hospital, Taiwan</p> <p>Susan Bull Oxford University, UK</p> <p>Phaikyeong Cheah Mahidol Oxford Tropical Medicine Research Unit, Thailand</p>	
17:30-17:30	<p>Announcement of 2018 Conference in Malaysia</p> <p>Closing Ceremony</p>	<p>Hans Amin Van Rostenberghe</p> <p>Kenji Hirayama</p>	



FERCAP General Assembly: 21 November 2018		
09:00-12:00	Welcome Remarks	Kenji Hirayama FERCAP Chair
	TAIRB: FERCAP Partner in Taiwan	Tang Tsang Hsieh TAIRB
	FERCAP Reports	Cristina Torres FERCAP Coordinator Kesara Na Banchang FERCAP Treasurer
	Demonstration of FERCAP Software	
	Recognition Ceremony	Juntra Laothavorn SIDCER Coordinator
	Closing Remarks	Kenji Hirayama FERCAP Chair
		Arthur Navarro Master of Ceremony