

台灣臨床研究倫理審查學會 函

會址：臺北市中正區仁愛路一段一號

聯絡人：高孟辰 小姐

聯絡方式：

02-2514-8990 (週一、週四)

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受文者：仁愛醫療財團法人大里仁愛醫院人體試驗委員會

發文日期：107年10月01日

發文字號：台倫審字第10700033號

速別：普通

密等及解密條件或保密期限：普通

附件：大會議程

主旨：本學會將於2018年11月18日至21日舉辦「第十八屆亞太地區倫理審查委員會論壇會」18th FERCAP Annual Conference 與 TAIRB 學術年會，誠摯邀請相關單位共襄盛舉，並歡迎加入本學會會員。

說明：

- 一、亞太倫理審查論壇(FERCAP)年會為亞太地區會員機構之年度盛事，今年「第十八屆亞太地區倫理審查委員會論壇會」首度移師台灣舉辦，由本學會與 FERCAP 籌備主辦，時間訂於11月18日至21日假林口長庚紀念醫院舉辦，邀請多位國際重量級專家及學者蒞臨演講，詳細活動議程附件，敬邀各相關單位一同共襄盛舉，請踴躍報名。

活動相關資訊如下：

pre-conference(會前工作坊)

11月18日(週日)下午13:00 - 17:00

※報名收費：NT1500

FERCAP Annual Conference(2018 FERCAP 國際年會)

11月19-20日(週一至周二)上午08:00 - 17:30

※報名費用：會員3000元、非會員4000元(原價6000元)

FERCAP General Assembly (FERCAP 會員大會)

11月21日(週三)上午9:00 - 12:00

收文

2018-10-05

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※本活動將提供與會證書

活動地點：林口長庚紀念醫院(333 桃園市龜山區復興街 5 號)，
復健大樓第一會議廳。

匯款方式：

戶名：台灣臨床研究倫理審查學會

銀行：合作金庫南京東路分行

帳號：1346-717-035981

銀行代碼：006

- 二、 本學會自 2009 年創會以來首次主辦年度學術年會，除邀請相關領域專家與會報告及討論最新研究與倫理審查趨勢外，另為在良好之研究倫理審查品質下，提升本國臨床試驗執行效率，特邀請相關生技醫療廠商一同與會，進行雙向溝通，以建立良好的合作關係。詳細課程內容請參考附件議程。

本年會活動相關資訊如下：

活動時間：11 月 18 日(週日)下午 08:30 - 15:00

活動地點：林口長庚紀念醫院(333 桃園市龜山區復興街 5 號)，
兒童大樓 K 棟 12 樓第三會議室。

※本課程將授與研究倫理學分 4 小時

報名費用：會員免費、團體會員 10 人內免費、非會員 NT500/人

匯款方式：

郵局劃撥 帳號：50143921

戶名：台灣臨床研究倫理審查學會

- 三、 報名資格：歡迎從事臨床試驗、生技醫療、IRB、受試者保護等相關領域之工作人員參加。
- 四、 報名時間：即日起本學會網頁線上報名至 2018 年 11 月 02 日(週五)，活動報名資訊請詳見學會網址：www.tairb.org.tw
- 五、 報名並繳費完成，請將匯款憑證寄至
學會信箱 tairb.2009@gmail.com，
由秘書處確認後發信通知，方為報名成功。報名收據一律於研討會當天在會議現場領取，若有任何問題請洽詢學會秘書。
- 六、 若貴機構或研究倫理相關工作人員尚未加入本學會，歡迎同時申請加入團體或個人會員，以享相關研討會報名優惠，並可促進研究倫理相關審查及委員會運作經驗之交流。

正本：衛生福利部疾病管制署人體研究倫理審查會、醫療財團法人辜公亮基金會和信治癌中心醫院人體試驗委員會、振興醫療財團法人振興醫院人體試驗委員會、醫療財團法人台灣血液基金會倫理委員會、財團法人神經醫學研究基金會人體研究倫理審查委員會、衛生福利部桃園醫院醫學倫理及人體試驗委員會、敏盛綜合醫院人體試驗委員會、壠新醫院人體試驗委員會、衛生福利部桃園療養院倫理委員、羅東聖母醫院人體試驗/醫學倫理委員會、國立陽明大學附設醫院人體試驗委員會、國立臺灣大學醫學院附設醫院新竹分院人體試驗委員會、澄清綜合醫院人體試驗委員會(澄清綜合醫院中港分院)、童綜合醫療社團法人童綜合醫院人體試驗委員會、光田醫療社團法人光田綜合醫院人體試驗委員會、仁愛醫療財團法人大里仁愛醫院人體試驗委員會、秀傳醫療社團法人秀傳紀念醫院人體試驗委員會、天主教中華聖母修女會醫療財團法人天主教聖馬爾定醫院醫學倫理暨人體試驗委員會、佛教慈濟醫療財團法人大林慈濟醫院研究倫理委員會、台南市立安南醫院-委託中國醫藥大學興建經營研究倫理委員會、衛生福利部嘉南療養院人體試驗委員會、衛生福利部草屯療養院人體試驗委員會、義大醫療財團法人義大醫院人體試驗委員會、阮綜合醫療社團法人阮綜合醫院人體試驗委員會、國軍高雄總醫院人體試驗委員會、安泰醫療社團法人安泰醫院人體試驗委員會、屏基醫療財團法人屏東基督教醫院人體試驗審查委員會、臺灣基督教門諾會醫療財團法人門諾醫院人體試驗暨研究倫理委員會、衛生福利部玉里醫院人體試驗委員會

副本：

理事長：

蔡甫昌

台灣臨床研究倫理審查學會
Taiwan Association of Institutional Review Boards

台灣研究倫理審查學會學術年會

時間：2018年11月18日（星期日）上午08點30分至下午15:00點

地點：林口長庚醫院兒童醫院K棟12樓第三會議室、簡報室

時 間	主 題	講 師
08:30~09:00	報 到	
09:00~10:00	開幕致辭： 蔡甫昌 理事長 台灣臨床研究倫理審查學會(TAIRB)	
	Keynote Speech(大會主題): 主持人：何橈通常務監事(醫學研究倫理基金會董事長) 汪志雄監事(國泰醫院麻醉科主任)	
	特定醫療技術檢查檢驗醫療儀器施行或使用管理 辦法(特管辦法)	CDE(邀請中)
	人工智慧與研究倫理	王志中常務理事 奇美醫院副院長
	HIPPA 和 Common Rule 之個資使用規範	陳怡安醫師 台大醫學院
10:00~10:30	綜合討論	
10:30~10:45	茶敘/海報時間	
10:45~11:45	主持人：張芳維常務理事（三軍總醫院澎湖分院院長） 李碧芳常務理事（成功大學醫學院）	
	NGS 研究之倫理審查	蔡甫昌理事長 TAIRB
	基因治療倫理審查	邀請中
	IRB 品質改善彰基經驗分享	蘇矢立理事 彰化基督教醫院
11:45~12:15	綜合討論 總結	
12:30~13:30	TAIRB 會員大會（午休）	
13:30~15:00	TAIRB 年會論壇 「研究倫理審查品質與效率之提升」 主持人陳恆德理事(CDE)、蔡甫昌理事長(TAIRB) 與談人： CDE 林首愈副執行長、廖姝婷理事長(TCRA)、IRPMA 會長、連群理事(元培醫事科技大學)、陳肇文理事（醫學研究倫理基金會執行長）...	



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
	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
08:45-10:00 Session 1	Update in National/International Guidelines	
	Session Chairs:	Fu Chang Tsai TAIRB President Vicente Belizario Vice Chair, FERCAP
	Declaration of Taipei 2016	Fu-Chang Tsai TAIRB President National Taiwan University
	Highlights of CIOMS 2017	
	Implications of Revisions of International Guidelines to Ethics Review	
10:00-10:30	Coffee/Tea Break	
10:30-12:00 Session 2	Promoting Good Practice in Science and Ethics	
	Session Chairs:	Chih Shung Wong Cathay General Hospital
	Ethical Issues in Biobanks and Personalized Medicine	Kenji Hirayama FERCAP Chair
	Setting Up a Public Health Practice Ethics Committee	Jacinto Blas Mantaring III University of the Philippines
	Use of Electronic Consent Forms for Better Participation	IQVIA
	Multi-country Perception about Information in the Informed Consent Form	Juntra Laothavorn SIDCER Coordinator
12:00-13:00	Lunch Break and Poster Viewing	
13:00-14:30 Session 3	Parallel Sessions	
	Ethical Challenges in	Ethics Education/
		Ethical Challenges In



	Clinical Research Venue 1	Information in Research Venue 2	Ethics Review Venue 3
	Parallel Session 3A	Parallel Session 3B	Parallel Session 3C
	Session Chair: Juntra Laothavorn SIDCER Coordinator	Session Chair: Vasantha Muthuswamy FERCAP Steering Committee (India)	Session Chair: Aphornpirom Ketupanya FERCAP Steering Committee (Thailand)
	<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 Saiful Islam et al., 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 Education in Taiwan: AREE Chien Chou, Taiwan 	<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
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	National Regulations and	Cross Straits Discussion



	Among Vulnerable Populations	Ethics Review	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: Magdarina Agtini FERCAP Steering Committee (Indonesia)	Session Chair: Tsang Tang Hsieh Changung 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	Parallel Sessions		
Session 5	Ethical Challenges in Continuing Review	Ethical Challenges in Innovative Research Design	Cross Straits Discussion on Clinical and Research 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 	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 	

	Reporting in RCTs Mahanjit Konwar et al., India <ul style="list-style-type: none"> • Measuring Impact of Offsite SUSARs Prajakta Auti et al., India 		Chih Yen Chen, Taiwan <ul style="list-style-type: none"> • 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 Session 6	Capacity Building in Research Ethics		
	Single/Joint Review of Multicenter Research Venue 1	Promoting Academic Research Venue 2	Assessment of REC Performance Venue 3
	Parallel Session 6A	Parallel Session 6B	Parallel Session 6C
	Session Chair:	Session Chair: Hans Amin Van Rostenberghe Universiti Sains Malaysia	Session Chair: Jiin Ger Taipei Veterans General Hospital
	Panel Discussion <ul style="list-style-type: none"> • Common Ethics Review of Multicenter Research in India Rajib Kishore Hazam et al., India • 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 	<ul style="list-style-type: none"> • Defining the Role of Academic Advisers Philippines • Improving Academic Publication through Good REC Procedures Indonesia • Compliance with Publication Ethics Junjira Laothavorn, Thailand 	<ul style="list-style-type: none"> • Factors Associated with Delayed REC Approval Thana Khawcharoenporn et al., Thailand • 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



	Ethics Committee in Thailand Aphornpirom Ketupanya, Thailand		
15:00-15:30	Coffee/Tea Break		
15:30-17:00 Session 7	Multiple Perspectives about Data Sharing		
	Session Chairs:	Vajira Dissanayake FERCAP Steering Committee (Sri Lanka)	Fung Wei Chang Tri-Service General Hospital, Taiwan
	Ethical Issues in Using Health Databases	AS Aswamy Universiti Sains Malaysia	
	Ethical Assessment of Big Data Health Research	Fung Wei Chang Tri Service General Hospital, Taiwan	
	Equitable Data Sharing	Susan Bull Oxford University, UK	
	Ethics and Best Practices in Sharing Health Research Data	Phaikyeong Cheah Mahidol Oxford Tropical Medicine Research Unit, Thailand	
17:30-17:30	Announcement of 2018 Conference in Malaysia	Hans Amin Van Rostenberghe	
	Closing Ceremony	Kenji Hirayama	



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