

出國報告（類別：開會）

參與第23屆亞洲及西太平洋分會亞太倫理
審查論壇(FERCAP)年會

**23rd International Forum for Ethical
Review Committees in the Asia and
Western Pacific Region (FERCAP)
Conference**

服務機關：國立成功大學醫學院附設醫院

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摘要

成大醫院人體研究倫理審查委員會(IRB)自2012年通過西太平洋分會亞太倫理審查論壇(FERCAP)認證後，時隔多年與台灣臨床研究倫理審查學會(TAIRB)一同參與FERCAP年會。本屆會議自 2023年 11 月 27 日至 11 月 29 日於馬來西亞吉隆坡馬來亞大學醫學中心舉行，由馬來亞大學醫學中心醫學研究倫理委員會(Universiti Malaya Medical Centre-Medical Research Ethics Committee (UMMC-MREC))主辦，主題為「創新研究之倫理實踐：挑戰與機會」(Ethical Research Practices Related to Innovative Research: Challenges and Opportunities)。共有來自18個國家共477位參與者(線上及實體)。此次會議除了邀請學術相關領域的學者專家進行專題演講(session)外，亦針對不同主題之研究安排研究分享(parallel session)，講題內容從倫理審查演進至近年較熱門之大數據、機器學習等相關倫理，同時涵蓋社會科學研究之相關議題，不僅提供與會人員有關倫理審查新知，並可透過現場提問由不同思考觀點互相討論交流。

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壹、目的

亞洲及西太平洋地區倫理審查委員會論壇(FERCAP, The Forum for Ethical Review Committees in the Asian and Western Pacific Region)於2000年1月12日在泰國曼谷成立，經過一群生物倫理學家和醫學專家的深思熟慮，旨在將行為和生物醫學研究的倫理審查更確實落實。FERCAP隸屬於泰國法政大學(Thammasat University)健康科學學院(Faculty of Allied Health Sciences)，它是世界衛生組織(WHO)熱帶病特別培訓和研究計劃(TDR)的一個項目，也是倫理審查能力發展戰略倡議(SIDCER)下的一個區域論壇。為了增進亞洲及西太平洋地區倫理審查品質，FERCAP除了每年舉辦國際年會外，還有相關課程訓練計畫(例如：參與者保護課程(HPPC)、標準作業程序(SOP)開發課程及調查和評估倫理審查實踐課程)及培訓。透過參與2023FERCAP年會(圖一)，不僅可以了解目前與倫理審查相關的新知及發展方向，同時可與來自不同國家與文化之學者交流，增進自己的視野，亦為此行之目的。



圖一、2023 FERCAP年會

貳、 會議過程

亞洲及西太平洋地區倫理審查委員會論壇今年於馬來西亞吉隆坡舉辦 2023 年會，參與方式同時有實體及線上兩種，會議日期自2023年11月27日至11月29日，本屆年會的主題為「創新研究之倫理實踐：挑戰與機會」(Ethical Research Practices Related to Innovative Research: Challenges and Opportunities)。第一天上午、第二天下午及第三天皆有安排多場全體參與的專家大型演講 (Session 1及6)，其餘以 75 分鐘為一個時段，共 4 個時段(Session 2~5)，同時於三個分場提供不同主題之學者專題分享(2A~2C，3A~3C，4A~4C，5A~5C)，供與會者選擇自己有興趣的議題參與，同時為促進交流，會場亦有海報展示(poster display)。第一天中午主辦單位舉辦歡迎午宴>Welcome Lunch)，邀請與會者穿著自己國家的傳統服飾，搭配歌曲及舞蹈表演，增添大會的色彩(圖二)。最後一天除了介紹此次主辦單位馬來亞大學醫學中心外，尚針對FERCAP過去一年之業務及財務向與會者報告，簽定與區域性夥伴組織締結合作之意願書，並對今年度認證通過之機構進行授證儀式。本次帶領全台灣各家IRB成員一同前往年會之台灣臨床研究倫理審查學會(TAIRB)亦為此次簽約之其中一員(圖三)。



圖二、Welcome Lunch來自泰國與會者表演



圖三、最後一天TAIRB與FERCAP簽訂MOU，TAIRB理事長發表感言

本屆年會議程摘要如下：

PROGRAMME, FERCAP INTERNATIONAL CONFERENCE 2023
Day 1: 27 November 2023 (Monday)
8:00 AM – 5:00 PM (Malaysian Time)
Venue: 13th Floor, Menara Selatan, Universiti Malaya Medical Centre

Time	Event		
8:00 AM	Registration		
9:00 AM	Opening Ceremony		
9:00 AM	National Anthem and Universiti Malaya Song		
9:05 AM	Welcome Remarks		
	<ul style="list-style-type: none"> - Professor Dr. Nik Sherina Hanafi, Conference Chairperson - Professor Dr. Kenji Hirayama, FERCAP Chairperson - Dr. John Reeder, WHO-TDR Director 		
9:25 AM	Welcome Remarks by Professor Dr. April Camilla Roslani, Dean, Faculty of Medicine, Universiti Malaya		
9:30 AM	Opening Remarks by Professor Dr. Nazirah Hasnan, Director, Universiti Malaya Medical Centre		
9:35 AM	Opening Gimmick		
9:50 AM	Keynote Address: Navigating Innovations in Research: Ethical Challenges Datin Dr. Sheamini Sivasampu, Director of the Institute for Clinical Research (ICR), National Institutes of Health, Ministry of Health, Malaysia		
10:15 AM	Session Break & Refreshments		
10:30 AM	Session 1		
	Plenary Session: Navigating Innovations in Research: The Ethical Roadmap Chairpersons: Professor Dr. Vicente Belizario, Jr.; Dr. Alex Phang		
	Plenary 1 Evolution of Ethical Standards in Innovative Research: A Historical Perspective Distinguished Professor Datuk Dr. Looi Lai Meng, Universiti Malaya Medical Centre Medical Research Ethics Committee		
	Plenary 2 Innovation and Global Collaboration in Research: The K-MEDI-Hub Experience Jin Young Yang et al., K-MEDI-Hub		
	Plenary 3 Safeguarding the Integrity of Innovative Research: Using Innovative Approaches to Address the Associated Ethical Issues Professor Dr. Jeremy Sugarman, Johns Hopkins Berman Institute of Bioethics		
	Plenary 4 Ethics Review of Big Data and Machine Learning Research Professor Dr. Juntra Laothavorn and Professor Dr. Cristina E. Torres, FERCAP		
12:30 PM	Welcome Lunch		
2:00 PM	Session 2: Parallel Sessions		
	Parallel Session 2A General Guidelines on Responsible Open Science Chairpersons: Dr. Phan Chia Wei Dr. Tsang Tang Hsieh	Parallel Session 2B Malaysian Initiatives in Clinical Research Chairpersons: Dr. Nurain Mohd Noor Dr. Azlan Husin	Parallel Session 2C Ethical Issues Involving Vulnerable Populations Chairpersons: Dr. Rumana Akhter Saifi Dr. Aphornpirom Ketupanya
	<p>Consortium led by University of Oslo Funded by the European Union Research and Innovation Programme <i>Rosemarie Bernabe, University of Oslo</i> <i>Lisa Haberlain, European Union Research Ethics Committees (EUREC)</i> <i>Judy Love Malundo, Migrants' Citizen Science Association, Norway</i></p> <ul style="list-style-type: none"> • Open Methods and Tools • Protection of Human Participants • Citizen Science • Open Access Publication 	<ol style="list-style-type: none"> 1. Setting Up the Ecosystem in First in Human Research <i>Audrey Ooi, Clinical Research Malaysia</i> 2. Development of the National Healthy Volunteer Registry <i>Chew Chun Keat, Institute of Clinical Research, Malaysia</i> 3. Feasibility of a Single IRB Model <i>Melvyn Chin, National Cancer Institute, Malaysia</i> 4. Conducting Site Audits for Compliance Review <i>Lee Keng Yee, National Institutes of Health, Malaysia</i> 	<ol style="list-style-type: none"> 1. Ventilator Allocation in a Low Resource Setting <i>Lenora C. Fernandez, University of the Philippines Manila</i> 2. Ethical Dilemmas in Psychiatry Admissions <i>Ng Chong Guan et al, Universiti Malaya</i> 3. Prisoners as Research Participants <i>Nur Hazwani Mohd et al, Clinical Research Centre, Malaysia</i> 4. Ethical Issues in Anthropological Research on Research on Ethnolinguistic Groups and Extant Communities <i>Mia. Teresa de Guzman et al, University of the Philippines Manila</i>
3:30 PM	Session Break		

3:45 PM	Session 3: Parallel Sessions		
	<p>Parallel Session 3A Patient-centric Research: Public Patient Involvement (PPI) / Stakeholder Engagement Chairpersons: Assoc. Prof. Dr. Julia Patrick Engkasan Dr. Fung Wei Chang</p>	<p>Parallel Session 3B Regulatory Compliance of Global Clinical Trials Chairpersons: Dr. Lee Keng Yee Mr. Pio Justine Asuncion</p>	<p>Parallel Session 3C Ethical Issues Related to Specific Research Topics Chairpersons: Dr. Mohammad Firdaus Abdul Aziz Prof. Im Hee Shin</p>
	<ol style="list-style-type: none"> Engaging Vulnerable Populations in Community-based Participatory Research: Lessons Learned from HIV <i>Dr. Nur Afiqah Mohd Salleh, Universiti Malaya</i> Ethical Challenges in Digital Data Collection in Community Engagement <i>Nor Hafzah Selamat et al, Universiti Sains Malaysia, Malaysia</i> Perception and Practice of Post-Trial Access among Research Stakeholders in Sub-Saharan African Countries, an EDCTP Funded Research <i>Yemisrach Zewdie, Armauer Hansen Research Institute (AHRI)</i> Challenges in Setting up the Research Ethics Consultation Services <i>Amnah Azahar et al, Universiti Teknologi MARA, Malaysia</i> 	<ol style="list-style-type: none"> Elevating Health Standards: A Sharing Session on WHO's Benchmarking Tool <i>Joseph Ali, Johns Hopkins Berman Institute of Bioethics</i> Inspection Findings to Harmonise the Processes of ECs in Malaysia <i>Nicholas Leow Chun Wei, National Pharmaceutical Regulatory Agency (NPRA), Malaysia</i> Exploring Medical Device Regulations during Its Entire Life Cycle <i>Yu-Hui Chen, Taipei Tzu-Chi Hospital</i> Responsible Conduct of Research & Functions of A Research Integrity Office <i>Chau De Ming, Universiti Putra Malaysia</i> 	<ol style="list-style-type: none"> Ethics Review of Genomic Research among Indigenous Peoples <i>Ma. Corazon de Ungria et al, University of the Philippines Diliman</i> Research Ethics Platform on Traditional Healthcare Systems <i>Arun T. AVP Research Foundation, India</i> Association between Research Design and Outcomes in Real World Evidence (RWE) Studies <i>Snehalata Gajbhaye et al., All India Institute of Medical Sciences</i> Ethical Issues on the Secondary Use of Clinical Samples: A Scoping Review <i>Jennifer Landicho, Research Institute for Tropical Medicine, Philippines</i>
5:00 PM	End of Day 1		

Day 2: 28 November 2023 (Tuesday)
8:00 AM – 5:00 PM (Malaysian Time)
Venue: 13th Floor, Menara Selatan, Universiti Malaya Medical Centre

Time	Event		
8:00 AM	Arrival of Delegates		
8:55 AM	Greetings and Announcements		
9:00 AM	Session 4: Parallel Sessions		
	<p>Parallel Session 4A Improving the Informed Consent Process Chairperson: Prof Dr. Noradinar Baharuddin Prof. Dr. Juntra Laothavorn</p>	<p>Parallel Session 4B Institutional Approaches towards Quality Review Chairperson: Dr. Tee Meng Yew Dr. Nur Atik</p>	<p>Parallel Session 4C Exploring Researcher Perspectives about Research Ethics Chairperson: Prof. Dr. Nik Sherina Hanafi Dr. Phantipha Wongwei</p>
	<ol style="list-style-type: none"> Analysis of informed consent documents for compliance with ICMR guidelines <i>Chaitali Chindalore et al, All India Institute of Medical Sciences, Nagpur</i> Identifying Domains That Affect the Capability of Children to Assent <i>L Ngo and JBV Mantaring, University of the Philippines Manila</i> Validation of the WHO Template for Informed Assent <i>Elizabeth Grace and Ma. Lucila Perez, Philippines</i> Electronic Informed Consent Criteria for Research Ethics Review: A Scoping Review <i>Mohd Yusmuidil Putera Mohd Yusof, University Teknologi MARA, Malaysia</i> 	<ol style="list-style-type: none"> Enhancing Review Efficiency of the Hospital Institutional Review Board <i>Wen-Pin Cheng et al, Taiwan</i> Management of Incomplete Protocol Submissions <i>Mei Shenghui et al, Beijing Tiantan Hospital, China</i> Capacitating Ethics Reviewers for Quality Review <i>Xiao Shuping et al, Beijing Tiantan Hospital, China</i> Concordance Rate among Reviewers in an IRB <i>Naraporn Prayoonwivat et al, Siriraj Hospital, Thailand</i> 	<ol style="list-style-type: none"> Researcher Knowledge, Attitudes and Practices (KAP) of Research Ethics in Nepal <i>Namita Ghimere et al, Nepal Health Research Council</i> Researcher KAP of Research Ethics in Malaysia <i>Wan Rosalina Wan Rosli et al, University of Cyberjaya, Malaysia</i> Assessment of Research Ethics Concepts among Post Graduate Students <i>Abdus Shakoor et al, Bangladesh Bioethics Society</i> Strategies to Promote Research Ethics in a Mega University <i>Abdul Rahman A, Universiti Teknologi MARA, Malaysia</i>
10:30 AM	Session Break		
11:00 AM	Session 5: Parallel Sessions		
	<p>Parallel Session 5A Good Implementation Research Practice Chairperson: Ms. Grazele Jenarun</p>	<p>Parallel Session 5B Technology Applications in IRB Operations Chairperson: Dr. Phang Kean Chang</p>	<p>Parallel Session 5C Reinforcing Responsible Conduct of Research Chairperson: Dr. Nishakanthi Gopalan</p>

	<p>Dr. Abraham Aseffa</p> <ol style="list-style-type: none"> Principles of Good Implementation Research Practice <i>Abraham Asseffa, WHO TDR</i> Ethical Issues in Implementation Research <i>Cristina E. Torres, FERCAP</i> Case Studies in Implementation Research <i>Ng Chirk Jenn, Duke-NUS & SingHealth Polyclinics, Singapore</i> <p>Open Discussion</p>	<p>Ms. Edlyn Jimenez</p> <ol style="list-style-type: none"> Ethics Review of Machine Learning Applications in Healthcare <i>Hazreen Harith, Universiti Putra Malaysia</i> Integrating Google-based Applications in Research Ethics Review <i>Florabelle Tagulling et al, University of the Philippines Diliman</i> Reducing Turn-around Time of Ethics Review <i>Joshua Narbo et al, Makati Medical Center, Philippines</i> The Effects of Electronic Review on the Ethics Review Process <i>Tzu Nien Chen et al, Mackay Memorial Hospital, Taiwan</i> 	<p>Mr. Rizky Harnawan</p> <ol style="list-style-type: none"> Gaps in Legal and Ethical Frameworks in Technology Driven Research <i>Deepa Paturkar, ILS Law College, India.</i> Improving Ethics Review of Sponsored Research <i>Halimah Mustafa, National Institutes of Health, Malaysia</i> Analyzing Serious Adverse Events <i>Yin Yen Wong, Universiti Malaya Medical Centre</i> Enigma of Post-Trial Access <i>M. Bhattacharjee, Lilavati Hospital and Research Centre, India</i>
12:30 PM	Lunch Break		
2:00 PM	<p>Session 6: Plenary Sessions Chairpersons: Professor Dr. Nik Sherina Hanafi, Dr. Nandini Kumar</p> <p>Plenary 5 Ethical Research in the Social Sciences, Humanities and Arts Professor Dr. Low Wah Yun, Universiti Malaya, Malaysia</p> <p>Plenary 6 Ethics Review Guidelines in Social Science Research Professor Dr. Juntra Laothavorn, SIDCER and Prof. Dr. Cristina E. Torres, FERCAP</p> <p>Plenary 7 Decentralized Clinical Trials (DCT): Prospects of Patient-Centric Research in Malaysia Ms. Asha Thanabalan, Clinical Research Malaysia, Malaysia</p> <p>Plenary 8 A Community Approach to Rethinking the Principles of Good Randomized Clinical Trials Rachel Hallett, The Good Clinical Trials Collaborative (GCTC), United Kingdom</p> <p>Plenary 9 AccessAfrica Guidelines on Post Trial Arrangements for International Clinical Trials Professor Rosemarie Bernabe, University of Oslo, Norway</p> <p>Summary</p>		
4:00 PM	Closing Ceremony and Announcement of Next Host Country		
5:00 PM	End of Day 2		

FERCAP General Assembly: 29 November 2023 (Wednesday)
9:00 AM – 5:00 PM (Malaysian Time)
Venue: Auditorium, 13th Floor, Menara Selatan, Universiti Malaya Medical Centre

Time	Event	
9:00 AM	Welcome Remarks	Kenji Hirayama, FERCAP Chair
	Awarding of Certificates of Appreciation	<p>FERCAP Conference Partners in Malaysia</p> <ul style="list-style-type: none"> Universiti Malaya Medical Centre (UMMC) Medical Research Ethics Committee (UMMC-MREC) Medical Humanities and Ethics Unit, Faculty of Medicine, Universiti Malaya (MedHEU) Universiti of Malaya Medical Center Clinical Investigation Centre (UMMC CIC) Faculty of Dentistry Medical Ethics Committee (FDMEC) Universiti Malaya Research Ethics Committee (UMREC) Ministry of Health Medical Research Ethics Committee (MOH MREC) Ministry of Health National Institute of Health (MOH NIH)
	UMMC as a Prime Site for Clinical Trial in Malaysia	Phan Chia Wei , Head of Clinical Investigation Centre, Universiti Malaya Medical Centre
	Exploring Multidisciplinary Research at UM: An Open Invitation for Collaborative Innovation	Sanjay Rampal , Deputy Dean of Research, Faculty of Medicine, Universiti Malaya
	FERCAP Reports	Cristina Torres , FERCAP Coordinator Kesara Na-Bangchang , FERCAP Treasurer
	Recognition Ceremony	Juntra Laothavorn , SIDCER Coordinator
12:00 PM	Closing Remarks	Kenji Hirayama, FERCAP Chair
1.00 - 5.00 PM	Update SIDCER Surveyor Training	WHO-TDR (by invitation)

***Note:** Venues for the various sessions are:
Opening Ceremony, Plenary session and General Assembly: Auditorium
Parallel Session A: Auditorium
Parallel Session B: Conference Room 2
Parallel Session C: Conference Room 1

參、會議重點摘要與心得

一、印象較深的是第一天下午的分場專題2C “Ethical Issues Involving Vulnerable

Populations”，此專題有四位研究者分享，其中包含馬來亞大學的精神科醫師，分享臨床上精神患者為易受傷害族群的倫理考量，及來自菲律賓的學者分享於原住民部落執行人類學相關之研究。有關精神患者臨床之倫理議題可能比我們想像的還要多，包含可能是非自願就醫、視病情須接受物理或化學性的約束限制、治療決定權可能須由家人代為行使等因而無法落實尊重自主的原則，其出院或結束治療是單純以病患為考量或需以大眾安全為考量，是否能夠兼顧病患自主與疾病治療之必要是臨床醫師們需評估的。有關原住民這類易受傷害族群和相關之社會學調查研究在目前工作較少遇到，因菲律賓之地緣關係，雖然是在同一國土上，有多達十幾種族之原住民，且每個種族都有著不同生活習慣及傳統，學者建議在執行研究前除了要先了解部落文化外，更重要的是事前之探查與拜訪，透過與部落中較有權威者之談話，建立與受試者之連結，研究執行會較容易且順利。

二、另外一場是第二天的分場專題5B “Technology Applications in IRB”，隨著科技日新月異，大數據及機器學習的相關研究也日益增加，這個專題涵蓋人工智慧(AI)應用於健康照護及使用GOOGLE作為倫理審查平台等的相關倫理考量，在AI設計過程中，首先有資料收集、資料保護、資料淨化及資料報告等步驟，接著會進入模組開發的階段，此時就需要訓練及校正模組，最後才是監測。AI開發需確保使用資訊的透明度、可解釋性和可理解性，且開發過程中亦須進行管理及改進，以確保不會造成心理或生理傷害，並善盡保護隱私和機密，減少政府、企業和民眾之間的權力差距及利益衝突，達到促進人類福祉、安全和公共利益的目的。對於受試者的保護最重要的還是維護其自主性及資料保密，透過與會者的互動提問中重新思考在取得研究資料及應用科技於審查時該如何同時兼顧受試者保護，IRB審查委員、行政人員也應吸收新知持續進步，才能達到保護受試者也保護研究團隊之功能。

肆、建議

- 一、本屆亞洲及西太平洋地區倫理審查委員會論壇同時有實體及線上兩種參與方式，不同專題的分場演講讓參與者可以自由選擇，課程內容豐富，增加了見聞也開闊了視野，會前從來沒有想過關於倫理審查可以有這麼多議題及研究面向。
- 二、本次很難得能夠和TAIRB一起參與，有機會和其他醫院的夥伴們交流，反思如何可以做得更好。建議提前告知出國報告須包含之內容及格式，於會議上即可先將相關資料收集整理，以利回國後報告之撰寫。
- 三、馬來亞大學醫學中心是馬來亞大學醫學院的教學醫院，也是馬來西亞最大、歷史最悠久的教學醫院，其臨床研究中心(Clinical Investigation Centre, CIC) 主要致力於馬來亞大學醫學中心臨床研究、臨床試驗及培訓，位置緊鄰醫學相關科部大樓，便利臨床醫師使用相關設備資源或諮詢，使其執行上可以更順利，以增加研究量能，與本校院提升教研設施與建設之理念相符。

伍、活動相片與說明



圖四、FERCAP2023年會第一天會場門口與TAIRB團員合照



圖五、FERCAP2023年會第一天中場休息與TAIRB團員合照



圖六、FERCAP2023年會會場