出國報告（出國類別：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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出國期間：112年11月25日至11月29日
報告日期：113年1月16日

摘要

　　成大醫院人體研究倫理審查委員會(IRB)與台灣臨床研究倫理審查學會(TAIRB)一同參與本屆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。

目次

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。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(圖一)，旨在對內能與台灣各家醫院交流，對外能增進國際研究倫理議題的了解，進而裨益本院國際能見度。

圖一、2023 FERCAP年會開幕

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，同時有實體及線上參與，共有來自18個國家共477位參與者。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)。

圖二、FERCAP2023年會會場

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，中間以 75 分鐘為一個時段，分別是(Session1:Plenary1~4，和Session6:Plenary5~9)；另有共4個時段(Session2~5)，同時於三個分場提供不同主題，如:知情同意過程、易受傷害族群研究、IRB科技運用、馬來西亞在地發起的臨床研究等，讓學者專題分享，(2A~2C，3A~3C，4A~4C，5A~5C)，供與會者選擇自己有興趣的議題參與。為促進交流，會場亦有海報展示(poster display)，並設立最佳研究獎以獎勵優秀的研究投稿者。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。可見下圖(二)TAIRB代表台灣與FERCAP簽訂合作備忘錄(MOU)，並由TAIRB理事長發表感言。

圖三、TAIRB張芳維理事長發表感言

本屆年會議程摘要如下：

CONFERENCE PROGRAM

Day 1: 27 November 2023 (Monday)

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
	- 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
	Consortium led by University of Oslo Funded by the European Union Research and Innovation Programme *Rosemarie Bernabe, University of Oslo* *Lisa Haberlain, European Union Research Ethics Committees (EUREC)* *Judy Love Malundo, Migrants' Citizen Science Association, Norway* • Open Methods and Tools • Protection of Human Participants • Citizen Science • Open Access Publication	1. Setting Up the Ecosystem in First in Human Research *Audrey Ooi, Clinical Research Malaysia* 2. Development of the National Healthy Volunteer Registry *Chew Chun Keat, Institute of Clinical Research, Malaysia* 3. Feasibility of a Single IRB Model *Melvyn Chin, National Cancer Institute, Malaysia* 4. Conducting Site Audits for Compliance Review *Lee Keng Yee, National Institutes of Health, Malaysia*	1. Ventilator Allocation in a Low Resource Setting *Lenora C. Fernandez, University of the Philippines Manila* 2. Ethical Dilemmas in Psychiatry Admissions *Ng Chong Guan et al, Universiti Malaya* 3. Prisoners as Research Participants *Nur Hazwani Mohd et al, Clinical Research Centre, Malaysia* 4. Ethical Issues in Anthropological Research on Research on Ethnolinguistic Groups and Extant Communities *Ma. Teresa de Guzman et al, University of the Philippines Manila*
3:30 PM	Session Break		

3:45 PM — **Session 3: Parallel Sessions**

Parallel Session 3A Patient-centric Research: Public Patient Involvement (PPI) / Stakeholder Engagement Chairpersons: Assoc. Prof. Dr. Julia Patrick Engkasan Dr. Fung Wei Chang	**Parallel Session 3B** Regulatory Compliance of Global Clinical Trials Chairpersons: Dr. Lee Keng Yee Mr. Pio Justine Asuncion	**Parallel Session 3C** Ethical Issues Related to Specific Research Topics Chairpersons: Dr. Mohammad Firdaus Abdul Aziz Prof. Im Hee Shin
1. Engaging Vulnerable Populations in Community-based Participatory Research: Lessons Learned from HIV *Dr. Nur Afiqah Mohd Salleh, Universiti Malaya* 2. Ethical Challenges in Digital Data Collection in Community Engagement *Nor Hafizah Selamat et al, Universiti Sains Malaysia, Malaysia* 3. Perception and Practice of Post-Trial Access among Research Stakeholders in Sub-Saharan African Countries, an EDCTP Funded Research *Yemisrach Zewdie, Armauer Hansen Research Institute (AHRI)* 4. Challenges in Setting up the Research Ethics Consultation Services *Amnah Azahar et al, Universiti Teknologi MARA, Malaysia*	1. Elevating Health Standards: A Sharing Session on WHO's Benchmarking Tool *Joseph Ali, Johns Hopkins Berman Institute of Bioethics* 2. Inspection Findings to Harmonise the Processes of ECs in Malaysia *Nicholas Leow Chun Wei, National Pharmaceutical Regulatory Agency (NPRA), Malaysia* 3. Exploring Medical Device Regulations during Its Entire Life Cycle *Yu-Hui Chen, Taipei Tzu-Chi Hospital* 4. Responsible Conduct of Research & Functions of A Research Integrity Office *Chau De Ming, Universiti Putra Malaysia*	1. Ethics Review of Genomic Research among Indigenous Peoples *Ma. Corazon de Ungria et al, University of the Philippines Diliman* 2. Research Ethics Platform on Traditional Healthcare Systems *Arun T. AVP Research Foundation, India* 3. Association between Research Design and Outcomes in Real World Evidence (RWE) Studies *Snehalata Gajbhiye et al., All India Institute of Medical Sciences* 4. Ethical Issues on the Secondary Use of Clinical Samples: A Scoping Review *Jeniffer Landicho, Research Institute for Tropical Medicine, Philippines*

5:00 PM — **End of Day 1**

Day 2: 28 November 2023

Time	Event
8:00 AM	**Arrival of Delegates**
8:55 AM	**Greetings and Announcements**
9:00 AM	**Session 4: Parallel Sessions**

Parallel Session 4A Improving the Informed Consent Process Chairperson: Prof Dr. Noradinar Baharuddin Prof. Dr. Juntra Laothavorn	**Parallel Session 4B** Institutional Approaches towards Quality Review Chairperson: Dr. Tee Meng Yew Dr. Nur Atik	**Parallel Session 4C** Exploring Researcher Perspectives about Research Ethics Chairperson: Prof. Dr. Nik Sherina Hanafi Dr. Phantipha Wongwei
1. Analysis of informed consent documents for compliance with ICMR guidelines *Chaitali Chindhalore et al, All India Institute of Medical Sciences, Nagpur* 2. Identifying Domains That Affect the Capability of Children to Assent *L Ngo and JBV Mantaring, University of the Philippines Manila* 3. Validation of the WHO Template for Informed Assent *Elizabeth Grace and Ma. Lucila Perez, Philippines* 4. Electronic Informed Consent Criteria for Research Ethics Review: A Scoping Review *Mohd Yusmiaidil Putera Mohd Yusof, University Teknologi MARA, Malaysia*	1. Enhancing Review Efficiency of the Hospital Institutional Review Board *Wen-Pin Cheng et al, Taiwan* 2. Management of Incomplete Protocol Submissions *Mei Shenghui et al, Beijing Tiantan Hospital, China* 3. Capacitating Ethics Reviewers for Quality Review *Xiao Shuping et al, Beijing Tiantan Hospital, China* 4. Concordance Rate among Reviewers in an IRB *Naraporn Prayoonwiwat et al, Siriraj Hospital, Thailand*	1. Researcher Knowledge, Attitudes and Practices (KAP) of Research Ethics in Nepal *Namita Ghimere et al, Nepal Health Research Council* 2. Researcher KAP of Research Ethics in Malaysia *Wan Rosalina Wan Rosli et al, University of Cyberjaya, Malaysia* 3. Assessment of Research Ethics Concepts among Post Graduate Students *Abdus Shakoor et al, Bangladesh Bioethics Society* 4. Strategies to Promote Research Ethics in a Mega University *Abdul Rahman A, Universiti Teknologi MARA, Malaysia*

10:30 AM	Session Break

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11:00 AM	Session 5: Parallel Sessions		
	Parallel Session 5A **Good Implementation** **Research Practice** Chairperson: Ms. Grazele Jenarun Dr. Abraham Aseffa	**Parallel Session 5B** **Technology Applications in** **IRB Operations** Chairperson: Dr. Phang Kean Chang Ms. Edlyn Jimenez	**Parallel Session 5C** **Reinforcing Responsible** **Conduct of Research** Chairperson: Dr. Nishakanthi Gopalan Mr. Rizky Harnawan
	1. Principles of Good Implementation Research Practice *Abraham Aseefa, WHO TDR* 2. Ethical Issues in Implementation Research *Cristina E. Torres, FERCAP* 3. Case Studies in Implementation Research *Ng Chirk Jenn, Duke-NUS & SingHealth Polyclinics, Singapore* Open Discussion	1. Ethics Review of Machine Learning Applications in Healthcare *Hazreen Harith, Universiti Putra Malaysia* 2. Integrating Google-based Applications in Research Ethics Review *Florabelle Taguiling et al, University of the Philippines Diliman* 3. Reducing Turn-around Time of Ethics Review *Joshua Nario et al, Makati Medical Center, Philippines* 4. The Effects of Electronic Review on the Ethics Review Process *Tzu Nien Chen et al, Mackay Memorial Hospital, Taiwan*	1. Gaps in Legal and Ethical Frameworks in Technology Driven Research *Deepa Paturkar, ILS Law College, India.* 2. Improving Ethics Review of Sponsored Research *Halimah Mustafa, National Institutes of Health, Malaysia* 3. Analyzing Serious Adverse Events *Yin Yen Wong, Universiti Malaya Medical Centre* 4. Enigma of Post-Trial Access *M. Bhattacharjee, Lilavati Hospital and Research Centre, India*
12:30 PM	Lunch Break		
2:00 PM	**Session 6: Plenary Sessions** Chairpersons: Professor Dr. Nik Sherina Hanafi, Dr. Nandini Kumar		
	Plenary 5 Ethical Research in the Social Sciences, Humanities and Arts Professor Dr. Low Wah Yun, Universiti Malaya, Malaysia		
	Plenary 6 Ethics Review Guidelines in Social Science Research Professor Dr. Juntra Laothavorn, SIDCER and Prof. Dr. Cristina E. Torres, FERCAP		
	Plenary 7 Decentralized Clinical Trials (DCT): Prospects of Patient-Centric Research in Malaysia Ms. Asha Thanabalan, Clinical Research Malaysia, Malaysia		
	Plenary 8 A Community Approach to Rethinking the Principles of Good Randomized Clinical Trials Rachel Hallett, The Good Clinical Trials Collaborative (GCTC), United Kingdom		
	Plenary 9 AccessAfrica Guidelines on Post Trial Arrangements for International Clinical Trials Professor Rosemarie Bernabe, University of Oslo, Norway Summary		
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)

Time	Event	
9:00 AM	**Welcome Remarks**	Kenji Hirayama, FERCAP Chair
	Awarding of Certificates of Appreciation	**FERCAP Conference Partners in Malaysia** • 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 **Juntra Laothavorn**, SIDCER Coordinator
	Recognition Ceremony	
12:00 PM	**Closing Remarks**	**Kenji Hirayama**, FERCAP Chair **Arthur Navarro**, Master of Ceremony

參、 會議重點摘要與心得

第一天上午的專家大型演講其中一場由FERCAP的內部學者發表與大數據和機器學習研究相關的倫理審查："Ethics Review of Big Data and Machine Learning Research"。講述大數據在醫療保健中的使用持續呈指數級增長，成為健康研究的重要資訊來源。大數據包括現實世界的日常實踐，如患者人口統計、共病、治療、保險記錄等。機器的可用性使得人工智慧智慧型裝置和Google類型應用程式中的廉價資料儲存成為可能。全球藥物開發目前涉及大數據研究，以尋找針對新出現和演變的疾病的有效治療方法。隨著遠距醫療成為與患者互動的標準模式，利用軟體應用程式的標準應用程式的使用也變得流行。人工智慧等電子機器、應用程式和軟體的使用給審查使用人工智慧等創新技術協議的研究倫理委員會帶來了重大挑戰。因此建議邀請獨立顧問或專家來解釋涉及研究目的技術及其使用方法，並確保所使用的人工智慧應用程式是值得信賴的，具有清晰的管理框架，能夠預想其使用情況、衡量其有效性並管理風險。IRB應分析所涉及的道德問題，以確保對弱勢參與者的高標準保護，最大限度地減少與自我管理相關的可能傷害的風險，確保保密性並在充分披露風險的情況下獲得知情同意。

關於易受傷害族群相關領域，同樣來自菲律賓的學者分享關於取得兒童同意的議題："Qualitative study to Identify Domains that Affect the Capability of Children to Assent"。菲律賓國家道德準則要求研究人員在參與任何研究之前確定兒童是否有能力同意與台灣一致。但根據現有的研究表明，年齡並非被用作孩子

是否有能力同意的唯一依據。因此，菲律賓的學者對五位專家進行訪談，包括小兒科醫師、倫理委員會成員、兒童心理學家、家長和教師。隨後，又邀請15位對兒童進行研究的研究人員進行了兩次焦點團體討論以進一步驗證。結果顯示教育、接受性和表達性語言、文化/種族、心理和情感方面的成熟度、社交媒體的接觸以及合併症是影響兒童同意能力的重要因素。雖然全世界仍通用年齡為兒童同意能力的基礎，但此次分享表明，有不同的領域影響兒童的同意能力，倫理委員會和研究應考慮這些因素，以便確保成功並保留同意過程的核心。

肆、 建議事項

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參與方式，邀請講者身分多元，除了有來自各國的專家學者針對本次主題演講外，亦有全球合作及臨床試驗的經驗分享，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。

二、 與會的人員和發表的內容雖然仍以醫療人員或醫學研究為多數，但是有關於社會科學的議題也佔一席之地，尤其針對原住民的人類學研究能提供不一樣的發想。雖然本會審查案件多為醫學研究，但不乏社會科學與相關研究方法。建議可在教育訓練加強這部分，為本會委員或行政人員增加相關知識與審查技巧。

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。如同本校院提升教研設施與建設之理念相符,本院臨床醫學研究中心、臨床試驗中心、人體研究倫理審查委員會、人體生物資料庫和受試者保護中心均位於門診6~7樓。將研究與受試者保護相關單位整合的用意,可多對研究人員宣傳,以期更加達到便民的目的。

圖四、FERCAP2023年會會場門

四、 本次很難得能夠和TAIRB的其他機構會員一起參與此次FERCAP年會,才有機會長時間和其他醫院甚至是其他醫學中心的夥伴交流。除了一起討論各IRB的現況、做法之外,也一起分享遇到的困難,進一步反思如何可以做得更好,也格外珍惜本院的資源與長官的支持。期望能有更多機會在各種國內、外會議、論壇或研討會跟國內外一流機構同業切磋交流。

圖五、FERCAP2023年會第一天中場休息與TAIRB團員合照