## PROGRAMME, FERCAP INTERNATIONAL CONFERENCE 2023 Pre-Conference Workshop: 26 November 2023 (Sunday) 1:00 PM - 5:00 PM (Malaysian Time)

Venue: 13th Floor, Menara Selatan, Universiti Malaya Medical Centre

Time	Event	Venue
1:00 PM	Registration & Lunch	13 <sup>th</sup> Floor, Menara Selatan, Universiti Malaya Medical Centre
2:00 – 5:00 PM	Workshop 1 Good Clinical Trials (GCT) Consortium Workshop	Auditorium *This will be a hybrid workshop with both online and physical participation options
	2) Workshop 2 A Practical Workshop on Preparing Ethics Applications	Conference Room 2 *Physical participation only
	3) Workshop 3 Ethical Research in the Social Sciences	Conference Room 3 *Physical participation only
	4) Workshop 4 Consent in a Snap: Accelerating Informed Decision-Making	Conference Room 1(A) *Physical participation only
	5) Workshop 5 Conflict of Interest in Research	Conference Room 1(B) *Physical participation only
5.00 – 7.00 PM	FERCAP Steering Committee Meeting	Conference Room 3

# PROGRAMME, FERCAP INTERNATIONAL CONFERENCE 2023 Day 1: 27 November 2023 (Monday) 8:00 AM - 5:00 PM (Malaysian Time) Venue: 13<sup>th</sup> 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> <li>Professor Dr. Nik Sherina Ha</li> </ul>	nafi, Conference Chairperson	
	- Professor Dr. Kenji Hirayama, FERCAP Chairperson		
0.05.444	- Dr. John Reeder, WHO-TDR		
9.25 AM		il Camilla Roslani, Dean, Faculty of Medic	
9:30 AM		rah Hasnan, Director, Universiti Malaya M	ledical Centre
9:35 AM 9:50 AM	Opening Gimmick	no in Decearch: Ethical Challenges	
9.50 AIVI	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		
10:20 444	Section 4		
10:30 AM	Session 1 Plenary Session: Navigating Innovation	ns in Research: The Ethical Roadman	
	Chairpersons: Professor Dr. Vicente Bel		
		g	
	Plenary 1		
	Evolution of Ethical Standards in Innovative Research: A Historical Perspective		
		ai Meng, Universiti Malaya Medical Centr	e 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	Parallel Session 2B	Parallel Session 2C
	General Guidelines on	Malaysian Initiatives in Clinical	Ethical Issues Involving Vulnerable
	Responsible Open Science	Research	Populations
	Chairpersons:	Chairpersons:	Chairpersons:
	Dr. Phan Chia Wei	Dr. Nurain Mohd Noor	Dr. Rumana Akhter Saifi
	Dr. Tsang Tang Hsieh	Dr. Azlan Husin	Dr. Aphornpirom Ketupanya
	Consortium led by University of Oslo	Setting Up the Ecosystem in First in	Ventilator Allocation in a Low Resource Setting
	Funded by the European Union Research	Human Research	Lenora C. Fernandez, University of the Philippines
	and Innovation Programme	Audrey Ooi, Clinical Research Malaysia	Manila
	Rosemarie Bernabe, University of Oslo Lisa Haberlain, European Union Research	Development of the National Healthy	Ethical Dilemmas in Psychiatry Admissions
	Ethics Committees (EUREC)	Volunteer Registry Chew Chun Keat, Institute of Clinical	Ng Chong Guan et al, Universiti Malaya 3. Prisoners as Research Participants
	Judy Love Malundo, Migrants' Citizen	Research, Malaysia	Nur Hazwani Mohd et al, Clinical Research
	<ul> <li>Science Association, Norway</li> <li>Open Methods and Tools</li> </ul>	Feasibility of a Single IRB Model	Centre, Malaysia
	Open Methods and Tools     Protection of Human Participants	Melvyn Chin, National Cancer Institute,	4. Ethical Issues in Anthropological Research on
	Citizen Science	Malaysia	Research on Ethnolinguistic Groups and Extant
	Open Access Publication	Conducting Site Audits for Compliance     Perior	Communities  Ma. Teresa de Guzman et al, University of the
		Review Lee Keng Yee, National Institutes of	Ma. Teresa de Guzman et al, University of the Philippines Manila
		Health, Malaysia	
0.00.514	Session Break		
3:30 PM	Session Dieak		

Parallel Session 3A Patient-centric Research: Public Patient Involvement (PPI) / Stakeholder Engagement Chairpersons: Assoc. Prof. Dr. Julia Patrick Engkasan Dr. Fung Wei Chang  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 Armah Azabar et al, Universiti Teknologi MARA, Malaysia  Parallel Session 3B Regulatory Compliance of Global Clinical Trials Chairpersons: Dr. Lee Keng Yee Mr. Pio Justine Asuncion  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. 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 Consultations Services Armah Azabar et al, Universiti Teknologi MARA, Malaysia  Ethical Issues Related to Specific Research Topics Chairpersons: Dr. Lee Keng Yee Mr. Pio Justine Asuncion  1. Elievating Health Standards: A Sharing Session on WHO's Benchmarking Tool Joseph Ali, Johns Hopkins Berman Institute of Bioethics Subdies Snehalata Gajbhiye et al., All India Institute for Medical Sciences Sended Stakeholders Studies Snehalata Gajbhiye et al., All India Institute for Medical Sciences Senders Institute for Tropical Medicine, Phillippines				
Patient-centric Research: Public Patient Involvement (PPI) / Stakeholder Engagement Chairpersons: Assoc. Prof. Dr. Julia Patrick Engkasan Dr. Fung Wei Chang  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 3. Perception and Practice of Post-Trial Access among Research Stakeholders in Sub-Saharan African Countries, an EDCTP Funded Research Permisrach Zewdie, Armauer Hansen Research Institute (AHRI) 4. Challenges in Setting up the Research Ethics Consultation Services Amnah Azahar et al, Universiti Teknologi MARA, Malaysia  Teknologi MARA, Malaysia  Regulatory Compliance of Global Clinical Trials Chairpersons: Chairpersons: Dr. Lee Keng Yee Mr. Pio Justine Asuncion Shrie Assoncion Chairpersons: Dr. Lee Keng Yee Mr. Pio Justine Asuncion Shrie Assoncion Chairpersons: Dr. Lee Keng Yee Mr. Pio Justine Asuncion Shrie Assoncion The Lee Keng Yee Mr. Pio Justine Asuncion  In Elevating Health Standards: A Sharing Session on WHO's Benchmarking Tool Joseph Ali, Johns Hopkins Berman Institute of Bioethics Institute of Bioethics Institute of Bioethics Inspection Findings to Harmonise the Processes of ECs in Malaysia Nicholas Leow Chun Wei, National Pharmaceutical Regulatory Agency (NPRA), Malaysia  Session on WHO's Benchmarking Tool Joseph Ali, Johns Hopkins Berman Institute of Bioethics Inspection Findings to Harmonise the Processes of ECs in Malaysia  1. Elevating Health Standards: A Sharing Session on WHO's Benchmarking Tool Joseph Ali, Johns Hopkins Berman Institute of Bioethics Inspection Findings to Harmonise the Processes of ECs in Malaysia  3. Perception and Practice of Post-Trial Access among Indigenous Peoples Accessamong Research Ethics Publical Session on WHO's Benchmarking Tool Joseph Ali, Johns Hopkins Berman Institute of Bioethics Session on WHO's Benchmarking Tool Joseph Ali, Johns Hopk	3:45 PM	Session 3: Parallel Sessions		
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 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  Session on WHO's Benchmarking Tool Joseph Ali, Johns Hopkins Berman Institute of Bioethics Processes of ECs in Malaysia Indigenous Peoples Ma. Corazon de Ungria et al, University of the Philippines Diliman 2. Research Ethica Platform on Traditional Healthcare Systems Arun T. AVP Research Poundation, India 3. Association between Research Design and Outcomes in Real World Evidence (RWE) Studies Sudies 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		Patient-centric Research: Public Patient Involvement (PPI) / Stakeholder Engagement Chairpersons: Assoc. Prof. Dr. Julia Patrick Engkasan	Regulatory Compliance of Global Clinical Trials Chairpersons: Dr. Lee Keng Yee	Ethical Issues Related to Specific Research Topics Chairpersons: Dr. Mohammad Firdaus Abdul Aziz
5:00 PM End of Day 1		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	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\(^1\)  4. Responsible Conduct of Research & Functions of A Research Integrity Office	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,
	5:00 PM	• , ,		

Day 2: 28 November 2023 (Tuesday) 8:00 AM – 5:00 PM (Malaysian Time) Venue: 13<sup>th</sup> 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		
	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	<ol> <li>Enhancing Review Efficiency of the Hospital Institutional Review Board Wen-Pin Cheng et al, Taiwan</li> <li>Management of Incomplete Protocol Submissions Mei Shenghui et al, Beijing Tiantan Hospital, China</li> <li>Capacitating Ethics Reviewers for Quality Review Xiao Shuping et al, Beijing Tiantan Hospital, China</li> <li>Concordance Rate among Reviewers in an IRB Naraporn Prayoonwiwat et al, Siriraj Hospital, Thailand</li> </ol>	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		
11:00 AM	Session 5: Parallel Sessions		
	Parallel Session 5A Good Implementation Research Practice Chairperson: Ms. Grazele Jenarun	Parallel Session 5B Technology Applications in IRB Operations Chairperson: Dr. Phang Kean Chang	Parallel Session 5C Reinforcing Responsible Conduct of Research Chairperson: Dr. Nishakanthi Gopalan

	Dr. Abraham Aseffa	Ms. Edlyn Jimenez	Mr. Rizky Harnawan
	Principles of Good Implementation Research Practice Abraham Assefa, WHO TDR     Ethical Issues in Implementation Research Cristina E. Torres, FERCAP     Case Studies in Implementation Research Ng Chirk Jenn, Duke-NUS & SingHealth Polyclinics, Singapore  Open Discussion	Ethics Review of Machine Learning     Applications in Healthcare     Hazreen Harith, Universiti Putra Malaysia     Integrating Google-based Applications in     Research Ethics Review     Florabelle Taguiling et al, University of the     Philippines Diliman     Reducing Turn-around Time of Ethics Review     Joshua Nario et al, Makati Medical Center,     Philippines     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 Announcemen	nt 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, 13<sup>th</sup> Floor, Menara Selatan, Universiti Malaya Medical Centre

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	
	Recognition Ceremony	Juntra Laothavorn, SIDCER Coordinator	
12:00 PM	Closing Remarks	Kenji Hirayama, FERCAP Chair Arthur Navarro, Master of Ceremony	

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