UNIVERSITI MALAYA

SIDCER Globalizing Ethics for Health Research

FERCAP

PUSAT PERUBATAN UNIVERSITI MALAYA

23rd FERCAP INTERNATIONAL CONFERENCE

Universiti Malaya Medical Centre
Kuala Lumpur, Malaysia
26 - 29 November 2023

"Ethical research practices related to innovative research: Challenges and opportunities."

CONTENT

WELCOME MESSAGE

DEAN OF FACULTY OF MEDICINE, UNIVERSITI MALAYA

On behalf of the Faculty of Medicine, Universiti Malaya, it gives me great pleasure to welcome you to FERCAP 2023, taking place in the exciting city of Kuala Lumpur, Malaysia.

The Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP) was conceived thirteen years ago in Bangkok, Thailand, by a group of bioethicists and medical experts. This was in order to foster better practice of ethical review in behavioural and biomedical research. FERCAP emphasizes collective wisdom and a systems approach to address important health research issues in Asia and the Western Pacific. It is fitting, therefore, that FERCAP 2023's theme is "Ethical Research Practices Related to Innovative Research Challenges and Opportunities."

Our esteemed speakers join delegates from all over the world, including ethics committee members, healthcare professionals, clinical researchers, and bioethicists, to engage in healthy debate. Such efforts embody FERCAP's global commitment to ethical vigilance in the face of innovation.

Universiti Malaya is pleased to host this year's programme in collaboration with FERCAP. Together, we will explore the educational and research opportunities that lie at the intersection of ethics and innovation. Our programmes are designed not only to educate, but also to empower delegates to navigate and shape the future of ethical health research.
Let us embody the spirit of learning and collaboration for the sake of mutual advancement as we embark on this journey. May the seeds of dialogue planted here flourish into substantial contributions to the field of health research ethics.

I look forward to the insights and breakthroughs that will arise from our time together.

Professor Dr. April Camilla Roslani
Dean, Faculty of Medicine
Universiti Malaya

WELCOME MESSAGE

DIRECTOR OF UNIVERSITI MALAYA MEDICAL CENTRE

Dear attendees,

As we convene at the Universiti Malaya Medical Centre for the significant FERCAP conference, we stand united by our dedication to ethical research practices amidst innovative challenges and opportunities. This gathering is a reflection of our collective commitment to upholding the integrity of research across the diverse tapestry of cultures and nations represented here.

FERCAP, since its inception, has been instrumental in fostering dialogue, enhancing understanding, and implementing robust ethical standards in health research within the Asian and Western Pacific regions. This conference, set against the vibrant backdrop of Kuala Lumpur, promises to be a convergence of minds eager to share knowledge, fortify ethical guidelines, and embrace the advancements of innovative research for the betterment of all.

Within these pages, you will find the distilled essence of our objectives, programs, and the spirit of collaboration that defines FERCAP. As we embark on this journey together, let us harness our collective wisdom to navigate the complexities of modern research with a moral compass that ensures the betterment of society.

Welcome to a pivotal platform for learning, sharing, and setting forth the principles that will guide the ethical dimensions of healthcare research. Let us make this conference not just a moment in time, but a milestone for the future.

Warm regards,
Professor Dr. Nazirah Hasnan
Director,
Universiti Malaya Medical Centre

WELCOME MESSAGE

CHAIRPERSON OF FERCAP

Welcome to the 23rd FERCAP international conference in Kuala Lumpur, Malaysia. It is my great pleasure to welcome all participants and guests, both in person and online, to our most important annual international meeting. The COVID-19 pandemic has changed its character after three years of viral mutations from alpha to omicron, that dramatically reduced the mortality rate in the world. Currently, we are entering a new post-corona era. We learned a lot from our own respective experiences during the past three years and we should utilize these insights as health stakeholders to develop innovative ideas to improve people's health and prepare for the next pandemic.

In this regard, there are several ideas frequently discussed at both international and domestic settings, such as 'Strengthening health systems, One health approach, and R&D for innovation.' FERCAP continues to update itself through its international networks to accelerate capacity development of ethical review of innovative clinical researches and community engagement approaches towards better evidence based health solutions in the Asia Pacific region. I hope that the 23rd FERCAP conference in KL will be able to provide new ideas, memorable experiences and delight in fellowship with our peers and co-workers.

Finally, I would like to give our sincere thanks to Universiti Malaya Medical Center and the organizing committee members for their untiring efforts to promote our advocacy for protection of human participants in scientific research. Thank you.

Professor Dr. Kenji Hirayama
FERCAP Chair
Professor Emiritus, Nagasaki University

FOREWORD

CHAIRPERSON OF MALAYSIA ORGANISING COMMITTEE

Dear friends and colleagues,
Welcome to 23rd FERCAP International Conference! I am honoured to welcome participants, both physically and virtually, from more than 16 countries to Kuala Lumpur.

We hope that the 23rd FERCAP International Conference will provide the opportunity for participants to share ideas especially in areas of innovative research and the implied ethical issues in the current times, in line with our conference theme “Ethical Research Practices Related to Innovative Research: Challenges and Opportunities.” We have prepared a programme that covers the wide array of areas that ethics review boards and committees would find relevant. At the same time, this is a wonderful opportunity to catch up and bond with friends and colleagues from your own countries and beyond.

I would like to express my deepest appreciation to the various parties who have made this conference possible, especially to the FERCAP conference secretariat and members of the FERCAP Organising Committee. The UMMC Medical Research Ethics Committee (UMMC MREC) has worked with UM Medical Research Ethics Committee (UMREC), UM’s Faculty of Dentistry Medical Ethics Committee (FDMEC), Faculty of Medicine’s Medical Health Research Ethics Unit (MedHEU) and UMMC’s Clinical Investigation Centre (CIC). My gratitude to the various departments of Universiti Malaya Medical Centre (Departments of Business Development, Information Technology, Engineering, Security, Facilities Management, and Corporate Relations), Universiti Malaya’s Faculty of Medicine, Department of Information Technology, Faculty of Creative Arts as well as to our sponsors, the Clinical Investigation Centre of UMMC, Clinical Research Malaysia and Klinsel.

I wish you all an enriching and fruitful conference!

Professor Dr. Nik Sherina Haidi Hanafi
Chairperson
23rd FERCAP Conference Organising Committee

FOREWORD

SCIENTIFIC CHAIR OF MALAYSIA ORGANISING COMMITTEE

Ladies and gentlemen, esteemed colleagues, and distinguished guests, it is my privilege and honour to welcome you all to the 2023 FERCAP International Conference. As we gather here today, we are bound by a collective purpose: the pursuit of ethical research practices in the face of emerging innovative challenges and opportunities.

We find ourselves at the nexus of an era defined by evidence-based policy and practice. Our commitment to scientific reasoning, combined with the integration of patient values and societal needs, underscores the pivotal role that research plays in our global community. Through research, we have the power to unlock new dimensions of knowledge and insights with the potential to greatly enhance human health and well-being.

Yet, with the monumental surge in knowledge comes the inevitable challenges. Our ever-evolving world now demands knowledge-based systems empowered by innovative technologies such as artificial intelligence. These novel approaches, while transformative, present a crucial crossroads: will they be wielded as instruments of unparalleled benefit or unintentional harm?This underscores the paramount importance of ethics in our field. It is our moral compass, guiding us in ensuring that the vast benefits of novel knowledge and technology are channeled for the greater societal good and upliftment.

Today, as members of the esteemed FERCAP community, we must come together to deliberate, collaborate, and pioneer the ethical frameworks that will shepherd us into the future. I am confident that with our collective wisdom and commitment, we can navigate these uncharted waters and ensure that innovation remains a boon, enhancing the quality of life for all.

Once again, welcome to the conference, and I eagerly look forward to the enriching discussions and groundbreaking insights this gathering will undoubtedly bring. Thank you.

Dr. Phang Kean Chang
Scientific Chair
23rd FERCAP Conference Organising Committee

FERCAP STEERING COMMITTEE

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FERCAP CHAIR
Professor, School of Tropical Medicine and Global Public Health and Institute of Tropical Medicine, Nagasaki University

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FERCAP Vice Chair
Professor, College of Public Health, University of the Philippines Manila

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Chairman, Commonwealth Health Professions and Partners Alliance

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Former Chair, Central Research Ethics Committee (CREC)

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Founding Chair, FERCAP

Juntra Karbwang Laothavorn (Thailand)
SIDCER-FERCAP Foundation President
Coordinator, Strategic Initiative for Developing Capacity in Ethical Review

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Krisna Veni Balakrishnan
Manager, Clinical Investigation Centre (CIC), Universiti Malaya Medical Centre

CONFERENCE SCHEDULE

NOVEMBER 2023		
26 (SUNDAY)	Pre-conference Workshops	1300 - 1700
	FERCAP Steering Committee meeting	1700 - 1900
27 (MONDAY)	Conference Proper	0800 -1700
	Welcoming Lunch	1230 - 1400
28 (TUESDAY)	Conference Proper	0800 - 1700
29 (WEDNESDAY)	FERCAP Recognition Program & General Assembly	0900 - 1200
	SIDCER Surveyor Training	1300 - 1700

PRE-CONFERENCE WORKSHOPS

26 November 2023 (Sunday)

Time	Event	Location
1:00 PM	Registration & Lunch	
2:00 PM	Workshop 1: Good Clinical Trials (GCT) Consortium Workshop	Auditorium
	Workshop 2: A Practical Workshop on Preparing Ethics Applications: Applying Ethical Principles Integrity in Research	Conference room 2
	Workshop 3: Ethical Research in the Social Sciences	Conference room 3
	Workshop 4: Consent in a Snap: Accelerating Informed Decision-Making	Conference room 1(A)
	Workshop 5: Conflict of Interest in Research	Conference room 1(B)
5:00 PM	End of Workshops	

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

*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

CONFERENCE PROGRAM

Day 1 (Continuation)

2:00 PM	**<u>Session 2:</u> 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		

CONFERENCE PROGRAM

Day 1 (Continuation)

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., Al 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**		

CONFERENCE PROGRAM

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		

CONFERENCE PROGRAM

Day 2 (Continuation)

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 Assefa, 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**		

CONFERENCE PROGRAM

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
	Recognition Ceremony	**Juntra Laothavorn,** SIDCER Coordinator
12:00 PM	**Closing Remarks**	**Kenji Hirayama,** FERCAP Chair **Arthur Navarro,** Master of Ceremony
1.00 - 5.00 PM	**Update SIDCER Surveyor Training**	**WHO-TDR (by invitation)**

ABSTRACTS

Keynote Address

NAVIGATING INNOVATIONS IN RESEARCH: ETHICAL CHALLENGES

Name: **Datin Dr. Sheamini Sivasampu**
Affiliation/Institution: **Director, Institute for Clinical Research (ICR), National Institutes of Health, Ministry of Health, Malaysia**

Presentation abstract:
This topic examines the dynamic of ethical challenges in innovative research. The limits of scientific inquiry are constantly being reshaped by new approaches and rapid technology breakthroughs, resulting ethical issues to be more intricate.In this presentation, we will look at the many ethical issues that researchers and ethicists confront, from the protection of health data to the incorporation of big data analytics and artificial intelligence. Drawing on real-world case studies, the difficult balance between scientific advancement and ethical responsibility is discussed. Furthermore, this address intends to contribute to a more thorough knowledge of the ethical landscape by shedding light on the ethical conundrums that arise in cutting-edge research, especially with sharing from the recently concluded WHO Global Clinical Forum. Finally, this talk aims to foster a nationwide and regional dialogue, a platform to assist researchers, ethicists and legislators to navigate the complex ethical conundrums related to the application of innovative research.

Session 1: Plenary 1

EVOLUTION OF ETHICAL STANDARDS IN INNOVATIVE RESEARCH: A HISTORICAL PERSPECTIVE

Name: **Distinguished Professor Datuk Dr. Looi Lai Meng**
Affiliation/Institution: **Chair, Universiti Malaya Medical Centre Medical Research Ethics Committee (UMMC-MREC), Universiti Malaya Medical Centre, Kuala Lumpur, Malaysia**

Presentation abstract:
Medical research has always left indelible marks in society through the ages. Notwithstanding many instances of reckless research before the advent of institutional and peer oversight, many of these have contributed to landmark advances, generating a high public regard for medical doctors and scientists. Jenner's vaccination experiment (1796) led to the British Vaccination Act (1840) and is acclaimed to have saved more lives than any other. However, this image of medical research was seriously blemished by a series of alarming misconducts in the 20th Century, leading to development of several research ethics guidelines. The Nazi human experiments of WWII lead to the WMA Declaration of Helsinki (1964), the Willowbrook Hepatitis study marked a turning point in experiments on children and the Tuskegee Syphilis Study led to the Belmont Report (1978). By the 1980s, ethics review became a necessary facet of research, and research ethics committees began to be established in most countries. Currently, the Declaration of Helsinki is the most widely accepted guideline on medical research involving human subjects and is adopted into the ICH Harmonised Tripartite Guidelines for Good Clinical Practice. The International Ethical Guidelines for Health-related Research involving Humans by CIOMS also provides guidance for the establishment of research ethics committees. In spite of rising awareness of accountability, recent public censure of high-profile studies involving stem cell research and gene-editing have turned the lens on the adequacy of ethics committees in oversight of studies engaging novel technology and innovations that are rapidly changing. Adherence to the fundamental principles of social value, and research integrity in research capacity-building is emphasised. It is equally important for ethics committees to comply with National Regulations and Guidelines, be engaged with peer-support activities and provide for continuing education and training of committee members, reviewers, and researchers.

Session 1: Plenary 2

ADVANCED STRATEGIES AND INNOVATIONS OF K-MEDI HUB: GLOBAL COLLABORATION AND WORLDWIDE EXTENSION

Name: **Yang JinYoung, Jeong Myeonghun**
Affiliation/Institution: **K-MEDI-Hub, South Korea**

Presentation abstract:
Korea's advanced healthcare industry is one of the core industries strategically supported by the national government. The healthcare industry in Korea is a cutting-edge technological industry integrating critical technologies such as BT, IT, and NT. The "Daegu-Gyeongbuk Medical Cluster" as K-Medi hub explores sources of future growth offering a comprehensive, global-scale research space and providing R&D support for the development and production of cutting-edge drugs and medical devices and offers a superior infrastructure complete with advanced hospitals, ample human resources, great educational facilities, and high-quality residential facilities. The K-MEDI hub strives to become the No. 1 R&D hub for the healthcare and pharmaceutical industries by firmly establishing the identity and direction of Medi cluster and conducting successful, world-class research activities. By pursuing noteworthy and groundbreaking projects, cultivating highly trained research personnel, and attracting top research institutes, the K-MEDI hub is dedicated to developing Medi-cluster as the world's best R&D hub in the advanced healthcare and as a cornerstone of the domestic and Global health industry. To step forward for the GLOBAL collaboration and Extension to outward, K-Medi hub introduce the pathway of strategies and suggest GLOBAL partnership worldwidely with all countries, institutes, associations belonging to SICER-FERCAP network.

Session 1: Plenary 3

SAFEGUARDING THE INTEGRITY OF INNOVATIVE RESEARCH: USING INNOVATIVE APPROACHES TO ADDRESS THE ASSOCIATED ETHICAL ISSUES

Name: **Professor Dr. Jeremy Sugarman**
Affiliation/Institution: **Johns Hopkins Berman Institute of Bioethics, USA**

Presentation abstract:
A robust conception of research ethics arguably necessitates safeguarding the integrity of research as well as the rights and welfare of those who participate in it. To meet these obligations, it is sometimes necessary to develop and implement creative approaches. It this talk, I will provide examples of innovative approaches that were used to address ethical challenges in three very different types of innovative research: stem cells, international HIV prevention research, and pragmatic clinical trials. Some of these solutions involve going beyond the individual and necessitate engaging responsible stakeholders.

Session 1: Plenary 4

ETHICS REVIEW OF BIG DATA AND MACHINE LEARNING RESEARCH

Name: **Professor Dr. Juntra Laothavorn & Professor Dr. Cristina E. Torres**
Affiliation/Institution: **FERCAP**

Presentation abstract:
The use of big data in health care continues to grow exponentially to become an important source of information for health research. Big data include real world daily routine practice like patient demographics, co-morbidities, treatments, insurance records, etc. The availability of learning machines enable cheap data storage in artificial intelligence smart devices and google type apps. Global drug development currently involves big data research to search for effective treatments for emerging and evolving diseases. While randomized clinical trials remain as the gold standard, scientists and health policy makers continue to examine the relevance of big data research to prove the effectiveness of new interventions in 'real world' patients. As telemedicine becomes a standard mode with patient interaction, the use of standard apps that utilize software applications have become popular.
The use of electronic machines, apps and software like Artificial Intelligence presents a major challenge for Research Ethics Committees that review protocols that use innovative technology like AI. There may be a need to invite an independent consultant to explain the technology andits use related to the objectives of the protocol. There should be assurance that the AI application to be used is trustworthy with a clear governance framework with the ability to map its use, measure its effectiveness and manage the risks. The REC should analyze the ethical issues involved to ensure high standards of protection of vulnerable participants, minimize the risks related to possible harm related to self-administration, ensure confidentiality and obtain informed consent with full disclosure of the risks.

Session 6: Plenary 5

ETHICAL RESEARCH IN THE SOCIAL SCIENCES, HUMANITIES AND ARTS

Name: **Professor Dr. Low Wah Yun**
Affiliation/Institution: **Universiti Malaya, Malaysia**

Presentation abstract:
Research ethics is an important topic to be addressed by social sciences and humanities researchers. The practice of ethics in a given research setting is complex ad pose some fundamentals ethical questions that a researcher must navigate. We do research based on ethical principles and practices for the good of humankind, expand scientific knowledge and enjoy the freedom of thought and expression. We aim to be objective in the research process as we strive to remain neutral and detached from the participants. Sensitivities and emotional engagement may be involved in research. Some researchers may lack empathy for their respondents and concern for those they research. Conscientious objection (one's beliefs or values versus one's duty to perform) is another ethical dilemma. As researchers, we have our own values, emotions and motivations that we bring to our research projects. One needs to be aware of these ethical dilemmas and the concept of self-reflexibility. Social sciences and humanities research is dynamic and progressive. Example, the rapid technological development and new innovations involved in social sciences and humanities research has also impacted the practice of ethics, e.g. online and social network research and the usage of data in public domain, e.g. profiling of users, generalisation of findings, stereotyping of respondents, etc. As researchers, we also need to build and maintain the trust of various stakeholders. All these pose ethical issues. Thus, researchers in social sciences and humanities need to identify and address ethical dimensions when involved in their research.

Session 6: Plenary 6

GUIDELINES IN SOCIAL SCIENCE RESEARCH: TOWARDS A COMPREHENSIVE ETHICAL REVIEW OF RESEARCH IN ASIA PACIFIC

Name: **Professor Dr. Juntra Laothavorn & Prof. Dr. Cristina E. Torres**
Affiliation/Institution: **SIDCER & FERCAP**

Presentation abstract:
In the ever-changing landscape of humanities and social sciences research in Asia and the Western Pacific, a critical need for comprehensive research ethics guidelines has persisted. FERCAP's mission is to develop tailored guidelines, ensuring research integrity and protecting the rights and dignity of participants. Originating in Thailand, the development of the "Ethical Guidelines for Human Research in Social Sciences and Humanities" drew inspiration from international ethical standards, such as the European Union's framework and the Good Clinical Practice Guideline (GCP) by the International Council on Harmonization (ICH). These guidelines offer a comprehensive ethical framework, encompassing various research scenarios and stakeholders. They address the ethical dimensions of research methodologies employed in social sciences, such as deception and blinded experiments, online research, archaeological research, school-based research, research involving prisoners, community-based participatory research, Ethnography, Psychology, Psychiatry, and Behavioral Sciences. The guidelines also discuss ethical approaches in social and humanities research like dealing with vulnerable populations, risk and benefit assessment, maintaining privacy and confidentiality, and getting informed consent. The document discusses issues related to the conduct of research such as research sites, unintended/unexpected incidental findings, misuse of research, protocol deviation and non-compliance, and conflict of interest. Finally, there is discussion of the responsibilities of research stakeholders that include the sponsor, the researchers, and the research ethics committees.
FERCAP is committed to adapting and translating the guidelines to the unique socio-cultural characteristics of the Asian and Western Pacific Region. The preliminary draft represents the collaborative start of a globally relevant, region-specific guidelines. FERCAP invites feedback from the academic community to enable these guidelines to become an important cornerstone of collaborative ethical research.

Session 6: Plenary 7

DECENTRALIZED CLINICAL TRIALS (DCT): PROSPECTS OF PATIENT-CENTRIC RESEARCH IN MALAYSIA

Name: **Asha Thanabalan**
Affiliation/Institution: **Clinical Research Malaysia, Malaysia**

Presentation abstract:
Decentralised Clinical Trials (DCT) have emerged as a game-changing approach to conducting clinical research, revolutionizing traditional trial methodologies and placing patients at the heart of the process. In response to the COVID-19 era, Malaysia has observed a growing trend in DCT activities, with a notable example being the delivery of investigational products (IP) directly to trial participants' homes.
DCT activities in Malaysia signify a pivotal shift towards patient-centricity and improved accessibility as it not only addresses challenges posed by traditional in-person trials but also enhances participant engagement and retention, thereby enriching the quality and reliability of research outcomes. As clinical researchers increasingly recognize the advantages of DCT in streamlining trial timelines, minimizing geographical barriers, and harnessing technological advancements, the method is gaining momentum as a preferred choice in the post-pandemic era by sponsor, investigator and as well as patients.
Discussing the future prospects of DCT, with a particular focus on Malaysia, this presentation aims to also highlight the collaborative efforts by clinical research stakeholders in Malaysia to establish guidelines for DCT implementation in the country. By embracing patient-centricity and leveraging technological innovations, DCT promises to elevate the standards of clinical trials, empowering the scientific community in Malaysia and beyond to usher in a new era of patient-focused research excellence.

Session 6: Plenary 8

A COMMUNITY APPROACH TO RE-THINKING THE PRINCIPLES OF GOOD RANDOMIZED CONTROLLED TRIALS: INFORMATIVE, RESPECTFUL, COLLABORATIVE, FEASIBLE AND WELL-MANAGED

Name: **Rachel Hallett**
Affiliation/Institution: **The Good Clinical Trials Collaborative (GCTC), United Kingdom**

Presentation abstract:
The Good Clinical Trials Collaborative (GCTC) has created new guidance to promote and enable high-quality, ethical randomized controlled trials (RCTs). Generating robust and reliable evidence from good RCTs is a critical tool in driving good healthcare across the world. Well-structured, relevant guidance can be the basis for individuals, organisations and health systems to create common goals, organise and focus efforts.
The Guidance was written by a community of diverse, global, multi-disciplinary RCT stakeholders and, after public consultation, was finalized and published on www.goodtrials.org in 2022. The Guidance text has since been used extensively in draft WHO Guidance on Best Practices for Clinical Trials.
The agreed Five Principles of Good RCTs are that they: - are designed to produce scientifically sound answers to relevant questions. - respect the rights and well-being of participants. - are collaborative and transparent. - are appropriate for their context. - manage quality effectively and efficiently.
The GCTC guidance takes a holistic view of the ethical responsibilities generated by an RCT. It offers universally applicable principles to help navigate potential tensions between capturing reliable data that is relevant to as large and diverse a population as possible and protecting the rights and wellbeing of participants. Nuances that are often seen as difficult to regulate can be tackled by this approach, such as - how benefits can be maximised and potential harms minimised in a proportionate and efficient way. - what roles ethical review boards and quality management systems should play to allow flexibility as well as safety and respect for all involved.
The GCTC guidance empowers users to make decisions about how to meet the objectives of these principles in their own context. For professionals, the Guidance can be a tool to prompt and justify tailored applications of the principles in a particular setting. However, the Guidance can also aid community engagement by improving understanding of what a good RCT looks like – and why – for non professional audiences.
We have embarked upon a period of advocacy, promotion and capacity development to support the embedding of the Guidance into RCT working practices. This includes the creation of a new global alliance of clinical trials networks, funded by a Wellcome award, with partners from research groups in South East Asia, South Africa and Latin America and the Caribbean.
Bringing together experienced and well-established RCT networks to explore effective application of the GCTC guidance in a variety of settings and contexts will help test and demonstrate its utility in improving practice. We hope that this Guidance can be a foundation of common understanding that good healthcare is informed by good evidence from good trials – and that it can help improve the standards of clinical trials and the way we collectively learn from and utilize their results.

Session 6: Plenary 9

ACCESSAFRICA GUIDELINES ON POST TRIAL ARRANGEMENTS FOR INTERNATIONAL CLINICAL TRIALS

Name: **Professor Dr. Rosemarie Bernabe**
Affiliation/Institution: **University of Oslo, Norway**

Presentation abstract:
The responsibility for post-trial access has been stipulated in various research ethics guidelines; however, stipulations vary in terms of what the content of the requirement is, to whom the requirement applies, and who ought to be recipients. Aside from or because of the pattern of disagreements, inconsistencies, and apparent compromise in the guidelines, the implementation of this ethical requirement has been put on hold. Utilizing a human development approach to post-trial access, The AccessAfrica Post-Trial Access Guideline will be the first guideline developed with the African clinical trial environment in mind. Concretely, it proposes 1) a unified, inclusive, and equitable definition of post-trial access; and 2) specifies the tasks of the various stakeholders in the implementation of post-trial access.

Session 2A

GENERAL GUIDELINES ON RESPONSIBLE OPEN SCIENCE

Name: **Rosemarie Bernabe, Lisa Haberlain, Judy Love Malundo**
Affiliation/Institution: **University of Oslo, Norway, European Union Research Ethics Committees (EUREC) & Migrants' Citizen Science Association, Norway**

Presentation abstract:
Science is quickly moving towards openness towards a movement called Open Science. The goal is share scientific processes and outputs beyond the traditional scientific sphere, thereby allowing for the possibility of the inclusion of non-traditional players in the scientific process. Examples of aspects of OS include open data, open methodologies, open access, open software, citizen science, among others. However, OS also raises its own set of ethical and integrity challenges. This session will be dedicated to the exploration of the Responsible Open Science General Guidelines, and how this set of guidelines can be relevant to research ethics review.

Session 2B1

SETTING UP THE ECOSYSTEM IN FIRST-IN-HUMAN RESEARCH

Name: **Audrey Ooi**
Affiliation/Institution: **Clinical Research Malaysia, Malaysia**

Presentation abstract:
Early phase trials are an essential step in clinical trials, purposed to study the safety profile of any investigational product. This abstract dives into the initiatives undertaken to ensure proper and comprehensive ethical review of early phase trials in Malaysia, particularly First-in-Human (FIH) trials.
Data from the past seven years shows less than 5% of total sponsored clinical trials in Malaysia are of Phase 1 trials, despite a large expansion of these trials in the Asia Pacific region. Understanding the gaps and challenges in conducting early phase trials, especially FIH trials, Clinical Research Malaysia (CRM), a Ministry of Health owned company, have spearheaded the Phase 1 Realisation Project (P1RP) between 2016 – 2021, which led to the development of national guidelines, accreditation of FIH trial sites, establishment of Scientific Review Panel in addition to people development.
The Scientific Review Panel (SRP) was established to support the Medical Research and Ethics Committee (MREC) in performing scientific evaluation of Phase 1 clinical trials on new drugs undertaken by and/or conducted in clinical trial sites in Malaysia. With international and local research experts in its panel, the SRP addresses the current gaps in having experienced reviewers/ evaluators for First-in-Human studies that would require a comprehensive review of the properties of IMPs, trial designs, pre-clinical data and initial human data (where applicable). Since 2020, the SRP has supported MREC in the review of four (4) of its studies [2 FIH studies & 2 First-in-Patient (FIP) studies].
CRM through its P1RP initiatives, has built on the country's Phase 1 ecosystem in Malaysia, in ensuring rigorous standards and procedures are in place to ensure safe and ethical conduct of FIH studies. Moving forward, CRM has embarked on the P1RP 2.0 which focuses on further expanding the capabilities of regulators, investigators and study coordinators as well as trial sites.

Session 2B2

DEVELOPMENT OF THE NATIONAL HEALTHY VOLUNTEER REGISTRY

Name: **Chew Chun Keat**
Affiliation/Institution: **Institute of Clinical Research, Malaysia**

Presentation abstract:
Malaysia has been actively conducting clinical trials involving healthy volunteers for over 30 years with more than 300 bioequivalence studies, phase 1 studies and vaccines studies. With the increasing number of trials, it becomes crucial to ensure the safety and well-being of these volunteers, especially when some may over-volunteer themselves by participating in multiple trials in different centres within a short timeframe. This could lead to excessive blood sampling and frequent unnecessary exposure to study drugs. To ensure the safety of these volunteers, it became essential to prevent over-volunteering and provide sufficient time for recuperation and drug elimination between trials.

The Malaysian Guideline for Phase 1 Unit Inspection and Accreditation Programme issued by National Pharmaceutical Regulatory Agency (NPRA) also indicated the need of a robust national monitoring system. Hence, the development of the National Healthy Research Volunteer Register (NHRVR) as a national monitoring system by the Institute for Clinical Research (ICR) in collaboration with NPRA, Institutional Review Board (IRB), and study centres is a significant step towards addressing this concern.

The NHRVR was launched on 2 July 2021 as a central online monitoring system to mitigate the risk of over-volunteering by tracking the active participation status of volunteers across different trial sites in Malaysia. This system allows authorized users from clinical trial sites to access and cross-reference information securely, ensuring data confidentiality and security. Before using the NHRVR to verify eligibility status for a new clinical trial, informed consent is obtained from the healthy volunteers. This ensures that volunteers are aware of their data being used for verification purposes, promoting transparency and ethical practice.

The key features of the NHRVR are:

- Accessibility: The platform is available 24/7, ensuring that tier-based authorized users from both government and private clinical trial sites can access and utilize it efficiently.
- Cross-referencing: The system enables real time cross-referencing at a national level, allowing the identification of volunteers who may have participated in other trials at different study centres.
- Web-based and high security: Being web-based and having high-security measures in place ensures the confidentiality and data security of the volunteers' information.
- Traceability and transparency: The platform provide a transparent and traceable record of a volunteer's participation history across different trials.
- Minimal data entry: To use the platform, minimal data entry is required, making it user-friendly and efficient for study centres and researchers.

By implementing the NHRVR, ICR demonstrates its commitment to prioritizing the safety of healthy volunteers by mitigating the risks associated with over-volunteering in clinical trials. This is particularly crucial when vaccine trials and phase 1 studies are gaining prominence in the country. Overall, the NHRVR is a significant advancement in ensuring the well-being and safety of healthy volunteers, and it exemplifies the Ministry of Health's dedication to addressing this important aspect of clinical trials in Malaysia.

Session 2B3

FEASIBILITY OF IMPLEMENTING A SINGLE INSTITUTIONAL REVIEW BOARD MODEL IN MALAYSIA

Name: **Melvyn Chin Yin Chung**
Affiliation/Institution: **National Cancer Institute, Malaysia**

Presentation abstract:
The responsibility of safeguarding the rights of human research participants is entrusted to Institutional Review Boards (IRBs). With over 30 years of experience in clinical research, Malaysia has a well-established and professional ethics and regulatory infrastructure. In 2016, there was a total of 162 industry-sponsored research (ISR) reviewed in Malaysia. This number had increased to 215 in 2021, most involving multiple centres for industry-sponsored trials. This was the highest number reported in 6 years, from 2016 until 2021, second only to Singapore in Southeast Asia. As clinical research continues to rise yearly in Malaysia, this can lead to potential delays in the commencement of multicenter trials due to the necessity of reviewing and approving trial protocols by multiple Institutional Review Boards.. As of May 2023, Malaysia's National Pharmacy Regulatory Agency (NPRA) oversees a total of fourteen Institutional Review Boards (IRBs) that are registered with the Drug Control Authority (DCA). These IRBs are responsible for reviewing all biomedical research and clinical trials involving human subjects. This aligns with the Malaysian Guidelines for Good Clinical Practice (Malaysian GCP) practised in Malaysia. The Medical Research Ethics Committee (MREC), part of the Ministry of Health (MOH) Malaysia, reviews all clinical research protocols involving MOH facilities. For the institutions that do not have their IRBs, the ethics application is sent to any registered IRB to be reviewed.The single institutional review board (sIRB) model is a system where only one IRB is responsible for reviewing and approving multi-site research that uses the same research protocol. It was developed to streamline and reduce the administrative burden on IRBs reviewing multisite studies and improve research startup timelines. A comprehensive analysis of literature, research publications, and related information was conducted and structured into a narrative review to explore the diverse ethical review approaches for the implementation of a single Institutional Review Board (IRB). This narrative review aims to identify the issues of the feasibility of implementing a single IRB model in Malaysia.
Keywords: Single institutional review board, sIRBs, multi-site research, institutional review boards

Session 2B4

EXPERIENCE OF SITE AUDIT: FINDINGS FROM THE COMPLIANCE REVIEW BY MEDICAL ETHICS & RESEARCH COMMITTEE (MOH), MINISTRY OF HEALTH, MALAYSIA

Name: **Lee Keng Yee, Nurain Md Noor, Mah Kar Yee**
Affiliation/Institution: **Medical Ethics & Research Committee (MOH), Ministry of Health, Malaysia**

Presentation abstract:
Starting from year 2017, Medical Research & Ethics Committee (MREC), Ministry of Health (MOH), Malaysia have conducted numerous site compliance reviews since 2017 to ensure the investigators comply to the Good Clinical Practice to protect the safety and wellbeing of trial subjects.
There were total of 10 compliances reviews done for 12 study sites, in which 6 were triggered compliance reviews and 4 were routine compliance reviews involving 23 industry sponsored research and 6 investigator-initiated research. The findings of compliance reviews are classified into critical, major and minor based on the effect of the findings to the safety, well-being and rights of trial participants and the data quality. The compliance review reports were then sent to Investigator to provide corrective actions and preventive actions (CAPA) as per stipulated in MREC's Standard Operating Procedures (SOP). The CAPA will then be reviewed and discussed in the MREC Full Board meeting till the closure of the compliance review.
From the experience, we found that it is crucial for compliance review to be done routinely as well as when complaints or safety concerns arise to ensure the safety and right of trial participants. From the findings, we could also identify issues that require change of policy and SOPs to ensure the better GCP compliance by the Investigators. It is also a great learning experience for MREC members to see the trial conduct at site other than reviewing the study documents during the MREC Meeting or when the studies are assigned to them. In addition, it is also a great opportunity for the investigators to clarify their doubts or hesitations with MREC when conducting trial at sites from the compliance review that had been conducted.
In conclusion, it is utmost important for ethics committee to conduct compliance reviews to ensure the quality of trial and protect the right, safety and well-being of trial participants.

Session 2C1

ETHICAL CHALLENGES IN VENTILATOR ALLOCATION DURING COVID-19 CRISIS LEVEL CARE IN A LOW-RESOURCE SETTING, SUBTITLE: WHO GETS THE LAST VENTILATOR?

Name: **Lenora Canizares-Fernandez**
Affiliation/Institution: **Division of Pulmonary Medicine, University of the Philippines Manila, Philippines**

Presentation abstract:
Health crisis-level situations, such as the COVID-19 pandemic, has brought the challenge of ethical allocation of scarce life-saving resources (e.g. mechanical ventilator) in the face of sudden demand by critically ill patients. The problem is heightened in low-resource countries with limited number of ventilators. This article analyzes the ethical challenges in mechanical ventilator allocation during the COVID-19 pandemic in low to middle-income countries (LMIC), such as the Philippines. Among the three rationing principles of substantive justice, maximizing the benefit of the limited and vital resource for the most in society is acknowledged by majority of public health experts to be the prevailing principle to guide resource allocation. In low-resource settings, such as low to middle-income countries, with pre-existing health inequities in health care resources and absence of legal framework supporting advance directives, the principle of maximizing benefit is tempered with proportionate need focused on the vulnerable population sectors that may have suffered from inequities even before the COVID-19 crisis. The procedural aspect of the allocation decision formulation and implementation should ensure community engagement with solidarity, openness, veracity, transparency and accountability as values to be consistently manifested. Painful decisions will still be made at the frontline on who will receive the life-saving ventilator or not, but, as long as there is transparency and community participation in these decisions, then the decision-makers will be able to live with these decisions without undue burden on their conscience.

Session 2C2

ETHICAL DILEMMAS IN PSYCHIATRIC ADMISSIONS: A MALAYSIAN PERSPECTIVE

Name: **Ng Chong Guan & Ting Sing Qin**
Affiliation/Institution: **Faculty of Medicine, Universiti Malaya, Malaysia**

Presentation abstract:
The complex cultural and religious landscape in Malaysia poses unique ethical challenges in psychiatric care to healthcare professionals and policymakers. We presented the ethical dilemmas in Malaysian psychiatry from various viewpoints, including involuntary admissions, prolonged stay, restraint, treatment, and AOR (at-own-risk) discharge. Addressing these challenges requires an interdisciplinary approach involving healthcare professionals, policymakers, and society. Clear guidelines, cultural competence training, and legislative reforms can enhance ethical practices, improve patient care, and ensure the protection of patients' rights in the diverse and evolving landscape of Malaysian psychiatric healthcare.
Keywords: Ethics, psychiatric, admission, Malaysia

Session 2C3

PRISONERS AS RESEARCH PARTICIPANTS: STUDY METHODOLOGIES AND ETHICAL CONSIDERATIONS - A SCOPING REVIEW

Name: **Nur Hazwani Mohd Jamili, Adeeba Kamarulzaman, Rumana Akhter Saifi**
Affiliation/Institution: **Faculty of Medicine, Universiti Malaya, Malaysia**

Presentation abstract:

Background: Historically, prisoners were exploited and abused in medical experiments. Over the decades, health research involving prisoners is increasingly prevalent after learning about its importance and benefits to society and prisoners. However, the research must be conducted ethically, to avoid the recurrence of exploitation and abuse of prisoners, with additional safeguards provided to protect vulnerable prisoners.

Objectives: To conduct a scoping review of the literature regarding health research involving prisoners as research participants in low- and middle-income countries, focusing on the ethical challenges and additional safeguards provided to overcome the challenges and protect prisoners. Methods: A scoping review guided by a five-stage framework by Arksey and O'Malley (2005). Online database search was conducted in three main databases - PubMed, Cochrane Library and Scopus using search terms covering ‘prisoners’ and ‘health research’. The selection of articles was guided by the PCC formula (Population, Concept, Context). Search results were reported in the PRISMA flowchart.

Results: 46 articles were selected for inclusion in the review. The ethical challenges mentioned in the articles were classified into study procedures, prison population, prison settings and ethics committee approval, resulting in several ethical issues being mentioned such as voluntariness in informed consent, undue influence and stigma. Surprisingly, coercion was not mentioned in any of the selected articles. Additional safeguards were inconsistently provided to the participating prisoners mostly to protect prisoners’ privacy and confidentiality and increase informed consent validity.

Conclusion: Research involving prisoners in low- and middle-income countries was conducted ethically with additional safeguards provided to protect prisoners and mitigate the anticipated ethical risks. Training for research stakeholders and legislative enforcement could further improve the ethical conduct of research in the prison population in these countries.

Keywords: prisoner, incarcerated, research ethics, people in prison

Session 2C4

RITUALLY COMMUNING WITH ANCESTORS, PREDECESSORS, AND EXTANT COMMUNITIES: AN ETHICAL CONSIDERATION IN CONDUCTING ANTHROPOLOGICAL WORK AMONG ETHNOLINGUISTIC GROUPS IN THE PHILIPPINES

Name: **Ma. Teresa G. De Guzman & Michael Armand P. Canilao**
Affiliation/Institution: **Department of Behavioral Sciences, College of Arts and Sciences, University of the Philippines Manila, Philippines**

Presentation abstract:
Promoting beneficence, avoiding maleficence, and protecting the autonomy, welfare, safety, and dignity of all study IP communities are among the most essential ethical norms that must be followed. Researchers must avoid indulging in ethnocentric prejudices and work to maintain a high level of objectivity at all times. Ethical assessment should be well-informed, impartial, and transparent so that full justification for the research proposal can be obtained.
In order to prevent unethical scientific inquiry, ethical review and regulations are considered indispensable. A small number of incidents of research misconduct, if left unchecked, can have far-reaching consequences for an academic field. Anthropologists are obliged to take into account the potential effects of their research on themselves and the community that they are studying and subsequently conduct their work in a manner consistent with ethical principles. Anthropologists have traditionally taken the side of the subordinate (rather than the dominant) and are thus able to comprehend the significance and prevalence of ethical quandaries. When doing ethnographic fieldwork, anthropologists must prioritize the production of research that adheres to ethical standards. Research fieldwork, undoubtedly influences the individuals under investigation; therefore, anthropologists are obligated to ensure that their research endeavors do not have adverse effects on their stakeholder individuals or communities. They must refrain from benefiting from the cultural group under study without the ability to reciprocate to them in a culturally meaningful manner.
Together with the National Commission on Indigenous Peoples (NCIP), the majority of the Philippines' ethnolinguistic communities have created operational processes that are culturally relevant and sympathetic. The paper will showcase some of these processes that are deemed decentralized, with localized entry points rather than top- down approach. Often, it also privileges the autonomy of “tribal councils” of indigenous groups. This process is directed towards researchers, especially anthropologists, who conduct studies among Indigenous Peoples (IP) communities, whose cultural norms and values may be different from those of the researcher. However, this may be problematic for review panels that lack in-depth expertise in certain places because laws may be applied differently depending on where they are enacted.
This paper will also look at latent (extant communities/ descendants) and manifest (ancestors and predecessors) permits through rituals that have to be conducted prior to anthropological research activity. This step is vital to establishing rapport and trust. Interestingly, such rituals also feature syncretism of elements.
Traditional customs and rituals exert a pervasive influence on multiple facets of life and demonstrate a deep connection within Indigenous Peoples communities. Numerous factors exert influence on the determination, endorsement, and authorization of research activities. Indigenous peoples are consistently endeavoring to identify and implement strategies that will effectively ensure the satisfaction of their ancestors. It is believed that by achieving this contentment, the ancestors will in turn provide answers, provide protection, and notably contribute to the success of research pursuits conducted by external parties

Keywords: Latent (extant communities/descendants), manifest (ancestors and predecessors), anthropology, ethnography, ecology, archaeology, syncretism (traditional and contemporary rituals)

Session 1

ENGAGING VULNERABLE POPULATIONS IN COMMUNITY-BASED PARTICIPATORY RESEARCH: LESSONS LEARNED FROM HIV

Name: **Nur Afiqah Mohd Salleh**
Affiliation/Institution: **Faculty of Medicine, Universiti Malaya, Malaysia**

Presentation abstract:
Community-Based Participatory Research (CBPR) is a collaborative approach that involves researchers working closely with community members to address health disparities and promote social change. This approach emphasizes the active involvement of the affected community in all stages of the research process. This participatory model fosters trust and empowers individuals, promoting community ownership of public health programs. It goes beyond traditional research by actively involving community members in decision-making, implementation, and evaluation. By integrating local knowledge and experiences, the CBPR approach enhances the relevance and sustainability of public health programs. Engaging vulnerable populations such as people who inject drugs (PWID) in low-barrier HIV services is paramount for preventing HIV and Hepatitis C transmission. The SEMARAK study in Malaysia applies CBPR principles by partnering closely with an NGO to address the unique challenges faced by PWID. It aims to recruit vulnerable PWID in a longitudinal, interventional cohort that links PWID to comprehensive HIV services, including medication-assisted therapy and needle-syringe exchange programs using a peer-based, patient navigation model. The NGO's expertise in outreach work in the community ensures culturally sensitive program development, emphasizing continuous community involvement. By integrating local evidence and insights, CBPR ensures the program aligns with the community's needs, fostering trust and active participation. Through collaboration with the NGO, the CBPR framework empowers the community, establishing a model for effective, community-driven HIV prevention and treatment programs among people who use drugs.

Session 3A2

ETHICAL CHALLENGES IN COMMUNITY ENGAGEMENT PROJECT AND DIGITAL DATA COLLECTION

Name: **Nor Hafizah Selamat, Nur Hafeeza Ahmad Pazil, Mohd Khairuddin Mohad Sallehuddin, Hasniza Mohamad Hassan, Zaireeni Azmi**
Affiliation/Institution: **School of Social Sciences, Universiti Sains Malaysia, Malaysia**

Presentation abstract:
Recent technological developments have fundamentally changed how data is gathered and maintained in various research projects and community Engagement (CE) is not an exception. In Malaysia, University-community engagement has been part of university's effort to encourage university's staff in addressing communities' issues and needs. Digital data collection is the process of collecting data electronically using existing technology such as smartphones, tablets, and other digital devices. While emerging digital technologies in data collection offer researchers' new avenues to collect real-time data, not much is known about current ethical dimensions, considerations, and challenges. The main ethical challenges surrounding community engagement and digital data collection will be explored in this paper along with recommendations for how to address them and encourage ethical behavior. Based on two community engagement projects conducted with homestay business communities in two different villages in northern and southern Malaysia, this paper will address the main ethical issues of privacy and informed consent. It is revealed that getting explicit agreement becomes increasingly important as technological devices capture more sensitive data from community members. The ownership and control of data is the second ethical concern. It is common in community engagement projects where researchers are to collect community-generated data, which raises concerns regarding who has ownership rights and the degree of community control over their data. Furthermore, there are ethical issues raised by the digital divide as not all communities have the same amount of digital literacy or access to technology. Without addressing these inequities, the use of data technology may worsen already-existing inequalities, putting vulnerable populations behind. Inaccuracy, prejudice, and biases in data present may be perpetuated by technological equipment. The possibility for data abuse and monetization is also an ethical concern. Communities run the risk of being used for financial gain as data becomes a valued asset, potentially compromising their interests. To address this issue, it is crucial to establish precise criteria for data usage, ensure that data is only used for the sake of the community, and consider data-sharing agreements that put the interests of the community first. To address these ethical issues effectively, a multi-pronged approach is recommended including comprehensive ethics training for stakeholders to ensure awareness and adherence to ethical principles and to have independent ethical committee such as JEPeM (USM) to ensure ethical compliance. By prioritizing informed consent, data ownership, inclusivity, accuracy, and fair usage, it is possible to foster responsible and ethical practices that empower communities and promote social good. Addressing these issues proactively will facilitate the integration of technology in community initiatives, fostering trust, and facilitating positive social outcomes.
Keywords: University-community engagement, ethical challenges, digital data collection, homestay business communities, JEPeM

Session 3A3

PERCEPTION AND PRACTICE OF POST TRIALS ACCESS AMONG INSTITUTIONAL REVIEW BOARD MEMBERS, RESEARCHERS, AND FUNDERS IN SUB-SAHARAN AFRICAN COUNTRIES: A QUALITATIVE STUDY

Name: **Yemisrach Zewdie**
Affiliation/Institution: **Armauer Hansen Research Institute (AHRI), Ethiopia**

Presentation abstract:
Post-Trial Access (PTA) is the provision of investigational product for clinical trial participants and the community after the trial ends. The implementation of PTA requires the inclusion of PTA plans in protocols and continuity in PTA plans from the trial planning stage up until its implementation. Even though it is one of the rights of research participants and the community, it is not sufficiently planned and implemented by most trials conducted in Sub-Saharan Africa.
PTA is well known in different countries but its implementation relies on the rule and guideline of each country. Brazil and Argentina are currently among the few where there are binding regulations to provide PTA; whereas in a few Low and Middle Income Countries (LMICS), such as Uganda, India, South Africa, non-binding national guidelines support the provision of PTA.
In the in-depth interview process of data collection knowledge gap in understanding of PTA, lack of written legal binding agreement between the researcher and funder, legally binding guideline in the country, weak ethical review system and regulatory bodies follow up on PTA implementation process are the main findings and identified gaps from study participants that represent IRB members, researchers and funders in sub-Saharan countries.
Training of Institutional Review Board members (IRB), researchers and funders; availability of written legal binding agreement between the researcher and funder; following strict research ethical review system and a written directive on follow up of PTA implementations by the regulatory bodies like Food and Drug Authority (FDA) will contribute a lot to maximize PTA implementation in Sub-Saharan countries.
Keywords: Post-Trial Access, researchers and trial participants

Session 3A4

ADDRESSING ETHICAL CHALLENGES IN RESEARCH THROUGH THE RESEARCH ETHICS CONSULTATION SERVICES (RECS) INITIATIVE: AN EXPERIENCE FROM UNIVERSITI TEKNOLOGI MARA (UITM)

Name: **Amnah Azahar & Aimi Nadia Mohd Yusof**
Affiliation/Institution: **Department of Medical Ethics & Law, Faculty of Medicine, Universiti Teknologi MARA, Malaysia**

Presentation abstract:
Conducting research encompasses a series of processes, starting from writing a proposal, obtaining ethical clearance, data collection and publishing findings where researchers often encounter various ethical issues in relation to informed consent, confidentiality, risk evaluation and data management. To alleviate the process, Emanuel et al. (2000) suggested a framework consisting of seven requirements for clinical research to be ethical. This framework provides a systematic guideline for ethical development and evaluation by investigators, review committee members, sponsors, and others by integrating traditional codes, declarations, and literature on research ethics involving human participants. However, despite the existence of the comprehensive ethical framework, researchers still face challenges in meeting the ethical demands of their projects.

To address this challenge, in 2020, the Department of Medical Ethics and Law at the Faculty of Medicine Universiti Teknologi MARA (UiTM) took the initiative to establish a research ethics consultation service (RECS), alongside the traditional teaching of research ethics at the undergraduate and postgraduate levels. The primary objective of this service is to provide a platform for faculty members, including academicians, researchers, and students, to seek guidance, support, and engage in discussions with experts regarding issues related to research ethics throughout their research journey. RECS offers individual ethics consultations and a two-day workshop aimed at equipping individuals involved in research with essential knowledge of research ethics.

Considering research ethics is a relatively new field in Malaysia, the establishment of such a service comes with its own set of challenges. These challenges include the need to raise awareness among faculty members, dispel misconceptions about the consultation process, and encourage researchers to share detailed information about their projects to assist with the consultation. Nevertheless, through this initiative, RECS has contributed to enhancing the ethical standards of research at UiTM. Hopefully, the experience shared can serve as a valuable resource for other institutions seeking to establish similar initiatives to address ethical challenges in research.

Session 3B1

ELEVATING HEALTH STANDARDS: A SHARING SESSION ON WHO'S BENCHMARKING TOOL

Name: **Joseph Ali**
Affiliation/Institution: **Johns Hopkins Berman Institute of Bioethics, USA**

Presentation abstract:
In September 2023, the World Health Organization (WHO) published the WHO tool for benchmarking ethics oversight of health-related research involving human participants. Jointly developed by WHO's Regulatory System Strengthening, Regulation, and Safety Unit and the Health Ethics & Governance Unit, it is intended to assist countries in evaluating their capacity to provide appropriate ethical oversight of health-related research. In addition to assisting in capacity-building efforts, the tool is intended to promote policy convergence and best practices in research ethics oversight, to enhance public trust in health research, and to ensure that the rights and safety of humans involved in health-related research are adequately protected. This session, led by a member of the WHO expert working group that supported the development of the tool, will introduce the WHO tool and place it in context.

Session 3B2

INSPECTION FINDINGS TO HARMONISE THE PROCESSES OF ECS IN MALAYSIA

Name: **Nicholas Leow Chun Wei**
Affiliation/Institution: **National Pharmaceutical Regulatory Agency (NPRA), Malaysia**

Presentation abstract:
The National Pharmaceutical Regulatory Agency (NPRA) is tasked with inspecting and listing ethics committees (ECs) with the Drug Control Authority (DCA). This listing is a requirement to allow the issuance of the Clinical Trial Import License (CTIL) and/or Clinical Trial Exemption (CTX) for unregistered investigational products to be imported into or manufactured in Malaysia. This is in line with the regulatory requirements as stipulated in the Control of Drugs and Cosmetics Regula(on (CDCR) 1984. The Bioequivalence & Ethics Committee (BEEC) Section, Centre for Compliance & Quality Control (CCQC) is tasked with the inspection on ECs for listing with the DCA since January 2020 after the NPRA restructuring. ECs inspected and complying to the listing requirements will be listed for 3 years. In this post-pandemic inspection cycle, 14 ECs were inspected between 2021 (1 EC), 2022 (7 ECs) and 2023 (6 ECs). From these inspections, a total of 244 observations were made where 59 (24%) were major and the remaining 185 (76%) were minor observations. The top three number of observations were found under Review Procedures of the EC (n=87; 35%), followed by Membership of EC (n=70; 29%) and Application Made to the EC (n=46; 19%). The most common major observations relate to the independence of the EC in the organisation as well as ensuring members are free of conflicts of interest. Since this cycle of inspection was done post pandemic, there were many recurrent observations related to compliance to established procedures and procedures not updated to reflect current practices.

Session 3B3

EXPLORING MEDICAL DEVICE REGULATIONS AND INTELLECTUAL PROPERTY PROTECTION THROUGHOUT THE ENTIRE LIFECYCLE OF MEDICAL DEVICES

Name: **Chen Yu-Hui**
Affiliation/Institution: **IRB of Taipei Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation, Taiwan**

Presentation abstract:
Due to the increasing global aging population, the United Nations website forecast overall life expectancy, from 72.6 years in 2019 to 77.1 years in 2050 in a significant trend. Since the growth of aging societies, medical devices play a crucial role in clinical surgeries and involve various healthcare applications for the elderly. The design of medical devices is driven according to need for diagnosis, treatment, prevention, and improvement of quality of life. In Taiwan, an independent Medical Device Management Act was implemented to regulate and manage medical devices on May 1, 2021. From the initial research and design stage, medical devices need to consider whether they comply with regulations, are suitable for medical purposes, ensure safety, require compatibility with other patents, and consider economic costs, among other factors. Therefore, it is crucial to devote efforts to protect their intellectual property so that prevent others from benefiting from the hard work and resources invested in their development. In exploring the International Medical Device Database, it is mentioned in the "Implant Files" section that global health authorities failed to timely protect millions of patients from harm caused by poorly tested implants. This marked the first-ever global examination of the medical device industry. These cases demonstrate that medical devices, being intended for medical purposes, inherently carry certain levels of risk and potential harm. The stringency of regulations is crucial in ensuring the protection of trial participants. We may present some case studies to explore the complete lifecycle of medical devices, discussion may focus on the regulations surrounding medical devices and the potential intellectual property protection involved. Throughout these processes, various stakeholders may be involved, including patients, physicians, manufacturers, Institutional Review Boards (IRBs), and others.
Keywords: Medical Device, Intellectual Property Rights, Patent, 510(K), MDR

Session 3B4

RESPONSIBLE CONDUCT OF RESEARCH AND FUNCTIONS OF A RESEARCH INTEGRITY OFFICE

Name: **Chau De Ming**
Affiliation/Institution: **Department of Biomedical Sciences, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia**

Presentation abstract:
In an era where research integrity is the foundation of scholarly pursuits, researchers are expected to conduct research truthfully. Establishing a Research Integrity Office (RIO) is vital to fostering research integrity within an institution. RIO serves many functions, and one of the key purposes is to provide updated policies and guidelines related to research integrity. These policies may include issues on data governance and the ethical use of technologies. A robust RIO should also frequently provide training on research integrity to all researchers in an institution, such as students or academics. Moreover, RIO also plays a role in managing breaches of research integrity policies or the Code of Conduct. These breaches may include severe issues such as research misconduct or minor breaches such as unethical authorship practices. This presentation will also highlight the Malaysian Code of Responsible Conduct in Research (MCRCR), a document that serves as the highest Code of Research Conduct in Malaysia, and it provides a framework for the function of RIO in an institution.

Session 3C1

CHALLENGES IN THE ETHICAL REVIEW OF GENOMIC RESEARCH PROTOCOLS INVOLVING PHILIPPINE INDIGENOUS PEOPLES (IPS)

Name: **Maria Corazon A. De Ungria, Justine Jay B. Marfil, Christopher John E. Limos, Najwa Hind B. Molina, Roben M. Omaweng, Edlyn B. Jimenez**
Affiliation/Institution: **University of the Philippines Diliman, Philippines**

Presentation abstract:
Ten years after the passage of Republic Act No. 10532 or the "Philippine National Health Research System Act of 2013" which established the system for the ethical review of protocols, the widespread adoption of this system for all research involving human participants remains to be realized. The factors affecting the acceptance of the value of ethics review for human participant protection are: 1) the misconception of the meaning of "health research" as only those involving clinical studies; 2) a sense of ownership, e.g., cultural, institutional, or personal, over specimens and information such as genomic data, of some scientists that creates friction with the human sources of the biological samples and their families/communities; and 3) the relative novelty of genetic research that has not been covered by policies of local institutions. These challenges are particularly pronounced when genetic research involves Philippine indigenous communities with their own cultural traditions that differ from the mainstream population. Given the presence of diverse indigenous peoples representing over 110 ethno-linguistic groups in the Philippines and the interest in studying their DNA which is believed to be less admixed due to their geographical and cultural isolation, there is an urgent need to study how scientists, especially foreigners who are less familiar with the indigenous way of life, follow Philippine laws implemented to protect the rights of human participants for all research conducted locally. This paper will report common 'unethical practice' of local and foreign genetic researchers, which include conducting research without clearance from a Philippine Health Research Ethics Board (PHREB) accredited Research Ethics Committee (REC) and from the National Commission on Indigenous Peoples (NCIP) which is mandated to protect IPs, many of whom remain economically and socially vulnerable; and the absence of a system of continuous reporting to the communities when new discoveries are made through secondary use of their samples in biobanks, and/or their information in global databases.
Keywords: Genomic Research, Philippine Indigenous Peoples, Ethical Review

Session 3C2

RESEARCH ETHICS PLATFORM FOR QUALITY RESEARCH OUTCOMES ON THE TRADITIONAL HEALTHCARE SYSTEM

Name: **Arun T.**
Affiliation/Institution: **AVP Research Foundation, Coimbatore, India**

Presentation abstract:
The international Ethical committees are doing a great job by monitoring health research worldwide. When it comes to Traditional medicinal Systems, the knowledge of healthcare that is based on practice-based evidence, is underutilised due to lack of ethical research and awareness. Most of the Traditional Medicine knowledge is not shared to healthcare practitioners as the trust is already broken by commercial exploitation of knowledge by pharma companies. and as a result of the current world's late adoption of evidence-based medicine. Due to a lack of supporting data, it is totally negligent that established medical systems have not been used to treat major health conditions.
During the pandemic, the world was in search of solutions other than the Major healthcare system which was exhausted due to the high number of ailing. Unfortunately, the quality research outcomes on the Traditional healthcare system were very few even though the practical evidence on management of ailments were much better than the published data.
For evaluating the research outcomes of the Traditional medicinal system, Ethics committees are using the Same guidelines which they use for the Allopathic Medical system which brings bias in the knowledge sharing and in evaluation of practical outcome. Region wise guidelines need to be created to monitor the research in Traditional healthcare systems, which in turn help the law authorities to take out the unethical medical practices in the name of tradition and beliefs.
Every medical practice beneficial for humanity needs to be ethically reviewed and adopted to provide health to mankind.
Focusing on Ayurveda, Traditional medical system from India, the discussion is made to develop a research ethics platform which helps the Traditional medical systems to publish the practice-based evidence without losing the intellectual property and copyright.
Keywords: Research Ethics platform, Ethical guidelines, Practice-based evidence, Traditional medical systems

Session 3C3

EFFECT OF STUDY DESIGN ON THE OUTCOME OF REAL-WORLD EVIDENCE STUDIES

Name: **Snehalata Gajbhiye**
Affiliation/Institution: **India Institute of Medical Sciences, India**

Presentation abstract:
Real-world evidence (RWE) is planned to provide data with relevance to clinical practice and is conducted to get answers to more real-life clinical practice-related questions. There are many data sources that can be utilized for carrying out RWE studies. They could be prospective and retrospective nature. The study's objective is to study the association of study design with the study's outcome. Also, we intend to study the assessment of therapeutic area, methodology and results of the drug related RWE studies and whether these studies represent the morbidity and mortality patterns of the world. The studies will be searched with the keywords 'clinical study' AND 'real world data' on Pubmed. The filters will select only papers with English language and species 'Human'. The additional filter that will be applied is the study types - 'Clinical study', 'Observational', Study published - 'last 10 years'.
The primary outcome measures is studying association of outcome of trial with the design of the study. The clinical study outcome will be categorized as positive or negative. This will be based upon the final conclusion made by the authors in the paper. The article stating the effectiveness will be classified as – positive, negative or cannot be concluded based on paper's conclusion about the RWE. The secondary outcome measures are the proportion of year of publication, therapeutic area where real world evidence, design of clinical study (prospective or retrospective/single or multicentre), objective studied, drug/s studied, treatment duration, overall study duration, outcome measures recorded by the study, sample size, special statistical tools used for eg. data cleaning and pre-processing in the form of imputation to fill in missing values, over-sampling for imbalanced data), results obtained (if not a clinical trial protocol), conclusion whether drug effective, funding agency. The second secondary measure is comparison of therapeutic area studied with the morbidity pattern. The data will be analyzed using descriptive statistics and the Chi-square test. We are currently analyzing the data and will present the study results in the conference.

Session 3C4

ETHICAL ISSUES ON THE SECONDARY USE OF CLINICAL SAMPLES: A SCOPING REVIEW

Name: **Jeniffer M. Landicho**
Affiliation/Institution: **Research Institute for Tropical Medicine, Philippines**

Presentation abstract:
When patients visit their physicians for consultation or treatment, it is common for physicians to collect patients' information, and medical history, and request laboratory tests either for diagnostic or therapeutic interventions. To perform a laboratory test, clinical samples, such as blood, urine, stool, and biopsy are obtained from patients. After the clinical diagnostic purposes have been fulfilled, the leftover clinical samples will either be discarded or stored allowing researchers to use them for secondary research. Clinical samples are a valuable source of information that may aid in the generation of new knowledge. However, the use of clinical samples for research poses various ethical issues especially when they were not extracted for research purposes nor consented to. We performed a scoping review to identify the ethical issues surrounding the use of clinical samples for research from different contexts and perspectives. We developed a search strings strategy to identify literature in PubMed, Scopus, Web of Science, and Google Scholar. Out of 3188 identified articles, 44 articles were included for final analysis. Based on the thematic analysis conducted on the published literature, four themes emerged regarding the ethical issues of the secondary use of clinical samples. These include knowledge and awareness; factors affecting the willingness to donate samples; consent; and governance and structures of the clinical samples.

Based on the result of the study, some individuals lacked knowledge and awareness about the potential of the clinical sample to be used for secondary purposes leading to confusion about the role of biospecimens in clinical and research settings. On the other hand, some researchers were not aware of the need to obtain IRB approval before they could reuse the clinical samples for research and viewed the application process as time-consuming while IRBs have their challenges in the evaluation and provision of IRB approval on the secondary use of clinical samples due to lack of guidance.

There were several factors that motivated individuals to donate their samples for research. This includes altruism; potential benefits to participants for donating the samples; culture, tradition, and belief; trust in researchers and institutions, privacy and confidentiality issues, doctor's instruction to provide the samples; timing of obtaining consent; and the model of consent being used to procure the sample.

Several ethical concerns were also identified involving consent. These were based on the model of informed consent documents being used to obtain the samples from the participants, from the consenting and reconsenting process, granting of approval from waiver of consent, revocation of consent, and withdrawal of research participation to the sharing of results or incidental findings to the participants.

Ethical concerns related to the governance of the clinical samples were also found in the management and storage of clinical samples, data sharing, and collaboration and ownership.

We synthesized all knowledge from the available literature from different contexts and areas to determine what are the ethical issues and their sources to use as a guide in conducting research using the secondary use of clinical samples ethically. Those who want to do policies are encouraged to consider this information in crafting their own national and institutional policies.

Session 4A1

COMPLIANCE PATTERN ANALYSIS OF INFORMED CONSENT DOCUMENTS IN ACCORDANCE WITH ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH FORMULATED BY THE INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR)

Name: **Chaitali Chindhalore, Ganesh Dakhale, Snehalata Gajbhiye, Ashish Gupta**
Affiliation/Institution: **All India Institute of Medical Sciences, Nagpur (MS), India**

Presentation abstract:

Background: Every research has some inherent risk and probability of harm or inconvenience to participants or communities. Ethical conduct of research depend on the voluntary expression of consent and adequate disclosure of information about the research in Informed consent documents (ICDs).

Objectives: To analyze ICDs of academic studies submitted to Institutional Ethics committee and to determine their compliance with National ethical guidelines for biomedical and health research laid down by ICMR and to assess change in compliance pattern. To determine readability of ICDs using Flesch-Kincaid grade level scale and Flesch reading ease (FRE) score.

Methodology: ICDs comprising of participant information sheet (PIS) and consent form of academic research projects submitted during 2020-22 were retrieved from the IEC office and analyzed in accordance with National ethical guidelines 2017 by ICMR which is also in conformity with those mentioned in other international standards like US Code of federal regulation. The information in the PIS is coded as “essential/additional elements present” scored as +1 or “essential/additional elements absent” scored as 0. Compliance score was calculated for each PIS. Readability of the documents was assessed by Flesch-Kincaid grade level scale and Flesch reading ease (FRE) score.

Result: Among 237 protocols submitted to IEC between 2020-22, 177 protocols were included in analysis. Most common were epidemiological studies (36.72%) followed by diagnostic studies (28.81%). Among proposals submitted, 31(17.51%) studies were funded by various government/private funding agencies. Vernacular translations of ICDs were present in significantly more number of studies in 2022 (x2 value 7.18, p = 0.02) as compared to 2020 and 2021. However, none of the study protocols includes back translation, or translation/back translation certification. Flesch's reading ease (FRE) score was 45.75±10.76 and Flesch-Kincaid grade level was 8.67± 1.44. Content analysis of PIS revealed that significantly more PIS submitted in 2022 mentioned expected duration of participation. (x2 value 6.95, p <0.001), benefit to patient/community (x2 value 26.63, p <0.001), disclosure of foreseeable risk or discomfort (x2 value 21.72, p <0.001), payment for participation (x2 value 21.72, p <0.001), identity of research team and contact details (x2 value 18.58, p <0.001). Surprisingly, none of the PIS mentioned alternative procedures or courses of treatment, insurance coverage for research-related or other adverse events, and provision of pre-test and post-test counselling in case of stigmatizing conditions. Compliance score was significantly better in 2022 as compared to 2020 and 2021.

Conclusion: Gradually ICDs became more compliant with ICMR guidelines. Due to lack of financial support, many of the researchers of academic studies are reluctant to disclose provision of remuneration for participation or free treatment of research related injury. Research institutions in the country should create a corpus for financial support. Sharing of model ICD template and regular training sessions on Good clinical practices will promote ethical conduct of research. Still, there is scope for improvement in ICDs regarding content and readability so that patients can comprehend facts easily to make informed decisions in a real sense.

Session 4A2

QUALITATIVE STUDY TO IDENTIFY DOMAINS THAT AFFECT THE CAPABILITY OF CHILDREN TO ASSENT IN THE PHILIPPINES

Name: **L Ngo, JBV Mantaring**
Affiliation/Institution: **University of the Philippines Manila, Philippines**

Presentation abstract:

Purpose: "Assent" is a term used to express willingness to participate in any activity by persons who are by definition too young to give informed consent but are old enough to understand the proposed research (1). Literature suggests that seeking children's assent has been put forward as a way to foster children's involvement in the healthcare decision-making process, fostering autonomy, reducing physical/psychological harm to the child, respecting the child as a human being, and fulfilling the universal rights of the child (2). Currently, the Philippine National Ethics Guidelines require researchers to determine if the children are capable to assent before they get involved in any study (1). Traditionally, age has been used as the sole basis whether a child is capable to assent. However, existing studies suggest otherwise and that age is not the sole basis to determine the their capability to assent. Hence, this paper seeks to identify the set of domains that affect the capacity of the pediatric population in the Philippines to actively participate in the assent process and ensure the success of assent.

Method: Using a deductive theory approach, five key informant interviews (KIIs) with key experts including a Developmental Pediatrician, Member of the Ethics Committee, Child Psychologist, Parent and Teacher. Subsequently, two focus group discussions (FGDs) were conducted to further validate the results of the KKI. 15 researchers who have done studies among children and experts in their field participated in this FGD. Comparative analysis of emergent themes were conducted using the NVivo software.

Results: In contrast with western setting where gender and prior experience of being subject in research and clinical setting affect capacity to assent, local experts revealed that locally, educational attainment as a surrogate for age, receptive or expressive language, psychological or emotional status and the background of upbringing do affect. Researchers have different opinion on the current National guidelines in terms of who can do the verbal, simplified and written assent. Though most still supports the age limit set by the PHREB, interestingly, a number of informants challenge it, and believe that even a younger age should and could already assent. Some believe that all older children needs to assent. The opinions of the informants are based on experiences and observations that can be classified under one or more the following domains: maturity, exposure to social media, ethnicity/culture, education, socio economic status, presence of any co-morbidities, prior general experience, ability to read and write, and understand the benefits and risks. The FGD participants strongly agreed that the ability to express or speak freely, followed by ability to understand the concept of "assent" and voluntariness after the explanation and ability to echo or explain what was said about the objectives of the research are integral to determine the capacity of child's competency to assent.

Conclusions: The domains identified are consistent with the KI and those identified in literature. Though locally it is notable that education, receptive and expressive language, culture/ethnicity, maturity in terms of psychological and emotional, exposure to social media, and co- morbidities are important factors that affect children's capacity to assent. Age is still used both locally and worldwide as a basis for competency among children for assent, but data and qualitative analysis have shown that there are different domains that affect the child's capacity to assent, which should be considered by ethical committees and researches in order to ensure the success and preserve the heart of the assent process.

Session 4A3

VALIDATION OF THE MODIFIED WHO TEMPLATE FOR INFORMED ASSENT, AND THE SELF-EFFICACY, DECISION-MAKING, AND KNOWLEDGE SCALES FOR UNDERSTANDING THE ASSENT PROCESS IN FILIPINO CHILDREN

Name: **Elizabeth Grace M. Perez, Ma Lucila M. Perez**
Affiliation/Institution: **Philippines**

Presentation abstract:

Introduction: Children are a vulnerable research. However, to date, there are no uniform informed assent and validated measures to evaluate the factors associated with the decision of Filipino children to involve themselves in research.

This study aimed to provide a validated informed assent form including reliable and validated questionnaires for evaluating self-efficacy, decision-making involvement, and knowledge in the assent process among Filipino children.

Methods: A cross-sectional study design was done involving children 7 to 17 years old from the adopted communities of the Philippine Children's Medical Center. Participants were stratified according to age group: 1) 7-11 years old, 2) 12-14 years old, and 3) 15-17 years old. A World Health Organization based informed assent was adapted and checked for readability via the Flesch Reading Ease (FRE) score and Flesch-Kincaid Grade level (FKGL). Linguistic validation to Filipino was done for the WHO assent, the adapted Decision self-efficacy scale, the RDMIS-R/C scale (19 items) on decision making involvement, and the Deaconess Informed Consent Comprehension Test. Reliability, face, content, and construct validity of the questionnaires were assessed.

Results: Fifty seven children participated. The informed assent had an FRE score of 75.1 and FKGL of 6.2. Upon translation, participants identified incomprehensible terms and suggested understandable alternatives. Cronbach alpha for the self-efficacy scale (0.77) and RDMIS-R/C tool (0.808) were acceptable. All items in the self-efficacy scale were essential as per face validity. Only items 4 and 10 did not meet the CVcritical (i.e. 0.571) for content validity; while, only items 2 and 4 were not significant as per Spearman Rho (0.05 two-tailed). Majority of items in the RDMIS-R/C were valid except for four items on face validity (i.e. 8, 12, 14n, 15), six items on CVcritical (i.e. 2, 6, 8, 11, 12, 14n), and one item (i.e. 2) on Spearman Rho (0.05 two-tailed). The knowledge scale, although valid did not meet the criteria for reliability.

Conclusion: A linguistically validated assent form was created. Validation of the questionnaires, resulted in a reliable 10- item self-efficacy and 14-item Decision making involvement questionnaire . The 6 concepts in the knowledge scale were retained with recommendation for item-per-item description per correct answer.

Further studies are recommended to better understand and enhance the assent process among the Filipino youth using the validated assent and questionnaires.

Keywords: Assent, ethics, validation, readability, self-efficacy, decision-making involvement, understandability, Filipino

Session 4A4

ELECTRONIC INFORMED CONSENT CRITERIA FOR RESEARCH ETHICS REVIEW: A SCOPING REVIEW

Name: **Mohd Yusmiaidil Putera Mohd Yusof, Teo Chin Hai, Ng Chirk Jenn**
Affiliation/Institution: **Institute of Pathology, Laboratory and Forensic Medicine (I-PPerForM), Universiti Teknologi MARA, Malaysia**

Presentation abstract:

Background: The research shows a growing trend in using an electronic platform to supplement or replace traditional paper-based informed consent processes. Instead of the traditionally written informed consent document, electronic informed consent (eConsent) may be used to assess the research subject's comprehension of the information presented. By doing so, respect for persons as one of the research ethical principles can be upheld. Furthermore, these electronic methods may reduce potential airborne infection exposures, particularly during the pandemic, thereby adhering to the beneficence and nonmaleficence principle. This scoping review aims to identify the ethics related criteria that have been included in electronic informed consent processes and to synthesize and map these criteria to research ethics principles, in order to identify the gaps, if any, in current electronic informed consent processes.

Methods: The search was performed based on internet search and three main databases: PubMed, SCOPUS and EBSCO. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation guideline was used to report this work.

Results: Of 34 studies that met the inclusion criteria, 242 essential original constructs were collated, and 7 concepts were derived. Digital content showed the highest percentage of collated original constructs (27%, n=65) followed by accessibility (24%, n=56), comprehension engagement (18%, n=43), autonomy (14%, n=34), confidentiality (11%, n=25), language (5%, n=13), and parental consent (1%, n=2). Twenty-five new items were synthesized for eConsent criteria which may provide guidance for ethical review of research involving eConsent.

Conclusion: The current study adds significant value to the corpus of knowledge in research ethics by providing ethical criteria on electronic informed consent based on evidence-based data. The new synthesized items in the criteria can be readily used as an initial guide by the IRB/REC members during a review process on electronic informed consent and useful to the future preparation of a checklist.

Keywords: Electronic informed consent; Institutional review board; Research ethics committee; Autonomy.

Session 4B1

ENHANCING REVIEW EFFICIENCY OF THE SHIN KONG WU HO-SU MEMORIAL HOSPITAL INSTITUTIONAL REVIEW BOARD

Name: **Wen-Pin Cheng, Kai-Lin Yang, Chiu-Mei Lin**
Affiliation/Institution: **Institute Review Board, Shin Kong Wu Ho-Su Memorial Hospital, Taipei, Taiwan**

Presentation abstract:
Efficient review of research involving human subjects is pivotal to safeguard ethical standards and expedite scientific progress. This abstract delves into the groundbreaking initiatives undertaken by the Shin Kong Hospital Institutional Review Board (IRB) to enhance review efficiency, highlighting the integration of an online review system, reduction of administrative review duration, and heightened awareness of review timelines among committee members. Recognizing the need for innovative measures, the Shin Kong Hospital IRB transitioned to an online review system, enabling researchers to submit applications and documents digitally. This shift significantly streamlined the submission process and enhanced transparency. Concurrently, administrative review duration was re-evaluated and condensed through strategic process optimization. To ensure committee members' active participation, the IRB instituted timely reminders to apprise them of impending review timelines. This step aimed to foster heightened engagement, preventing unnecessary delays and contributing to an efficient review process. Comparing the year 111 to the previous year 110, the impact of these transformations was noteworthy. The average operational days of IRB in year 111 were markedly reduced. The average number of days for exempt review was shortened from 9.3 to 6 days, the average number of days for expedited review was shortened from 29.1 to 18.2 days, and the average number of days for general review was shortened from 44 days to 32.9 days. This improvement underscores the effectiveness of the integrated changes in enhancing review efficiency without compromising the rigor of ethical oversight. The Shin Kong Hospital IRB's experience showcases the positive outcomes achievable through digitalization, process optimization, and proactive communication. As the landscape of medical research continues to evolve, the lessons learned from this transformative journey provide valuable insights for other institutions seeking to enhance their review processes, fostering a more efficient and responsible approach to ethical oversight.

Session 4B2

MANAGEMENT OF INCOMPLETE PROTOCOL SUBMISSIONS

Name: **Mei Shenghui**
Affiliation/Institution: **Beijing Tiantan Hospital, Capital Medical University, China**

Presentation abstract:

Introduction: Formal review occupied about 50% of the whole time during ethical review in our hospital. Improving efficiency of formal review could significantly shorten the time for ethical review.

Methods: The common problems in the formal review were identified. The reasons for these problems were analyzed and specified solutions and experience-based prescription were given out to overcome these problems.

Results: Common problems identified in the formal review including incomplete submissions, non-compliant seals and signatures, inadequate qualifications of researchers and team, delayed submissions and other problems. The reasons for incomplete submissions include insufficient preliminary research results, avoidance of responsibility, insufficient ability, insufficient energy, insufficient responsibility and insufficient experience. The specified solutions and experience-based managements were listed as follows: Training and punishment for avoidance of responsibility; CRC talent cultivation, system building, training, assessment, and screening for insufficient ability; reasonable workload and adding stuff for insufficient energy; clarify responsibilities and evaluation for lack of responsibility; improving working environments, giving respect, career development and increasing salaries for high CRC mobility; electronic system with clear processes and document templates, communication platform and setting ethics specialist for lack of experience during material submissions.

Conclusions: During ethic review, the reasons for incomplete submissions including insufficient preliminary research results, ability, energy, responsibility and experience. Both long-term and short-term management strategies should be considered to diminish incomplete submissions. The management strategies given out above might be useful for others to follow.

Session 4B3

CAPACITATING ETHICS REVIEWERS FOR QUALITY REVIEW

Name: **Xiao Shuping**
Affiliation/Institution: **Beijing Tiantan Hospital, China**

Presentation abstract:

Introduction: Clinical research assumes an indispensable role in advancing clinical medicine, underscoring the critical need for enhancing its management and perpetually exploring positive and effective innovative practices. Ethical review stands as an indispensable phase in the conduct of clinical research. To ensure the standardization and high-quality execution of clinical studies, a comprehensive scientific and ethical review is imperative to protect the rights and safety of research participants.

Speech content:

Introduction to the Construction and Operation Mechanism of the Ethics Committee at Beijing Tiantan Hospital;

Addressing issues and challenges encountered in past ethical review processes;

Proposal for the establishment of an ethical commissioners system by the Institutional Review Board of Beijing Tiantan Hospital to expedite the ethical approval process;

Objectives and Impact of an ethical commissioners system:

Focus on enhancing the training of additional ethics professionals and clinical research experts.

Elevating awareness regarding the critical importance of ethical review;

Effectively increasing researchers' knowledge and understanding of the legal and regulatory dimensions associated with ethical review;

Continuous optimization of management strategies for ethics specialists:

Iterative improvements in management strategies to accumulate valuable experiences for the advancement of clinical research in other medical institutions;

Potential contributions of these experiences towards the progress of clinical medicine.

Conclusion:

Strengthening the training and management strategies of ethics reviewers not only addresses existing challenges in ethics review but also presents a feasible avenue to enhance the quality of clinical research in medical institutions.

Session 4B4

CONCORDANCE OF THE RESEARCH PROJECT REVIEWS BY THE SIRIRAJ INSTITUTIONAL REVIEW BOARD

Name: **Peeraya Chaowalitwong, Supattra Dakham, Adun Bunsi, Sriwimon Manochiopinig, Naraporn Prayoonwiwat**
Affiliation/Institution: **Human Research Protection Unit (HRPP), Siriraj Hospital, Thailand**

Presentation abstract:

Introduction: Siriraj Institutional Review Board (SIRB) consists of 99 members. Fifty regular members sit in 4 different panels. A protocol with more than minimal risks will be reviewed by at least 2 independent reviewers and, whenever indicated, presented and discussed in the convened meeting. Each reviewer performs the review according to the Standard Operating Procedures version 7.1 (2017). Research studies with greater than minimal risk or involving vulnerable subjects are reviewed full board. In addition, one layperson will review the participant information sheet (PIS) and the consent information form (CIF) and provide recommendations during the convened meeting. Other types of study mostly undergo expedited reviews. Protocols will be determined as (1) approval, (2) minor or (3) major revisions required before approval, and (4) disapproval. If any of the 2 primary reviewers for an expedited review determined the protocol as Category 3 or 4, the protocol will be reviewed in the convened meeting for a consensus. Determination of each protocol depends on each reviewer's views and experiences. SIRB has 91 members with scientific backgrounds of 20 different

Concordance 2023-07-22 fields of expertise. Maintaining the homogeneity of the 4 different panels of committees is crucial for the quality assurance of SIRB. Only with information can a successful quality improvement be achieved. Therefore, discordance in opinions was investigated to delineate any factors contributing to the discrepancy.

Rationale: A concordance rate in the determination of protocol by 2 reviewers, with and without additional reviews in the convened meeting, was studied.

Materials and methods: A descriptive, retrospective study on the results of the determination on protocols submitted for SIRB approval in 2020 was performed. The study was approved by SIRB (Protocol No. 900/2564; exempt)

Session 4B4 (Continuation)

Presentation abstract:

Results: There were 1,067 protocols, classified as full board and expedited reviews in 233 (21.8%) and 834 (78.2%) protocols, respectively. No protocol was exempted. Most protocols (432, 40.5%) were retrospective chart reviews. Observational studies and questionnaire-based studies comprised of 188 (17.6%) and 126 (11.8%) protocols, respectively. The remaining 321 protocols were clinical trials (72, 6.7%) and test/experimental (249, 23.3%). Overall concordance was found in 673 protocols (63.1%). For the full board reviews, concordance rate between the 2 reviewers and the convened meetings, was 68.2% (159 of 233 protocols). All but 3 protocols were in Category 2. A total of 74 protocols showed discrepancy. Thirty-two protocols which at least one primary reviewer determined as Category 1 (by one reviewer and by both reviewers in 23 and 9 protocols, respectively), were re-classified as category 2. Reasons for the adjustment included laypersons' comments to revise PIF, additional recommendations from the meeting attendees on study rationales and methodology. Thirty-six protocols which one primary reviewer determined as Category 2, were re-classified as Category 3. For this group, determination by the two reviewers as Categories 1 and 2, 2 and 2, 2 and 3 were given in 1, 14 and 21 protocols, respectively. Safety concern was the main reason. For the expedited reviews, concordance rate was 61.6% (514 of 834 protocols). Number of protocols in Category 1, 2 and 3, were 64, 446 and 4, respectively. Discordance was found in 320 protocols (38.4%). Because at least one reviewer determined as Category 3 in 32 protocols, this mandated a final decision by the convened meeting. After discussion, the consensus was Category 2, 3 and 4 in 13, 17 and 2 protocols, respectively. When assessing the risks of the studies, concordance rate by full board and expedited reviews were 69.1% and 80.7%, respectively. With the benefits, they were 57.1% and 78.9%, respectively.

Conclusion: We found that concordance in the determination of protocol approval between two primary reviewers and the convened meeting consensus was over 60% in both full board and expedited reviews. In a convened meeting, invaluable comments from the experienced board members provided additional recommendations to improve the quality of protocol reviews. Information from this study will be used for the planning of educational courses for IRB members.

Keywords: human research protection, Institutional Review Board, quality improvement

Session 4C1

KNOWLEDGE, ATTITUDE AND PRACTICE OF RESEARCH ETHICS AMONG RESEARCHERS OF NEPAL

Name: **Namita Ghimire, Santoshi Adhikari, Subhanshi Sharma, Richa Acharya, Rojina Basnet, Shashi Verma, Pradip Gyanwali**
Affiliation/Institution: **Nepal Health Research Council, Ramshah path, Kathmandu, Nepal**

Presentation abstract:

Background: Health Research is an important tool for sustainable development. However, these researches should be conducted in accordance with the ethical principles. Research ethics helps to achieve the balance between advancement in science and protection of human subjects' rights. So, the objective of this study was to assess the knowledge, attitude and practice of research ethics among researchers of Nepal.

Methods: An online based cross-sectional study among 441 researchers applying for ethical approval in Nepal Health Research Council from January 2017 to August 2021 was done. Simple random sampling was done to obtain proportionate composition of researcher from each area of research. Semi structured questionnaire was used for data collection. Obtained data were entered in Ms Excel and analyzed using SPSS 23.0.

Results: The mean age of the respondents were 36.9±9.5 years. More than three fourth of the participants (79.1%) had training in research. Specifically, half of the participants (50.4%) had training in the area of research ethics. Almost 1/10th of the participants were unaware (8.8%) about the National Ethical Guideline for Health Research. The mean knowledge score was 10.7 ± 1.8. More than half of the participants (51.0%) believed that ethical review process delays the research and makes it harder for the researcher however majority of them (97.0%) agreed that researchers should have training in the area of research ethics. Among the participants, 16.8% had pursued research activity before obtaining the ethical approval. Majority of the participants (95.9%) had obtained informed consent from the study participants while conducting research while only half of them (50.6%) provided the copy of the consent to the study participants.

Conclusions: More than half of the respondents (56.5%) had adequate knowledge on research ethics. Although majority have positive attitude towards research ethics; training in the area of research ethics and awareness regarding the national ethical guideline and practice of research ethics was not adequate among the researchers which indicates the need of training and support in the area of research ethics.

Keywords: knowledge, attitude, practice, research ethics

Session 4C2

KNOWLEDGE, AWARENESS AND ATTITUDE TOWARDS HUMAN RESEARCH ETHICS AMONG RESEARCHERS IN MALAYSIA

Name: **Wan Rosalina Wan Rosli, Hehmanayagi Nadaraja**
Affiliation/Institution: **Faculty of Pharmacy, University of Cyberjaya, Malaysia**

Presentation abstract:

Introduction: In conducting research especially with the involvements of human, the research needs to be guided with the fundamentals of ethical principles. Research ethics is a term most widely used for principles of proper conduct during research thought and action processes and for the safety of human subjects. However, there is still lack of research on the knowledge regarding importance of research ethics among researchers and acceptability of Research Ethics Committee (REC) by researchers. So, this research aims to evaluate the Knowledge, Awareness and Attitude of researchers regarding research ethics and Research Ethics Committee (REC). Objectives. The primary goal of this study is to determine knowledge, awareness and attitude regarding human research ethics among researchers in Malaysia. **Methodology**: This cross- sectional study was conducted via Uniform Resource Locator (URL) in Facebook group such as (Doctorate support group, UPM postgraduates' group, Master & Ph.D. study in Malaysia group), WhatsApp and Instagram. The data was analysed using SPSS Software Version 26. The survey was done in Malaysia with a total of 200 participants. The convenience sampling method was used for data recruitment according to inclusion and exclusion criteria. **Results and Discussion**: Findings shows majority of respondent is postgraduate student 59.0% (N=188) followed by lecturer 21.5% (N=43). Result showed that among 200 respondent 61.0% (N=120) obtained high knowledge, whereas 64.0% (N=128) obtain positive attitudes towards research ethics. Moreover, all the respondent (N=200) showed high awareness on research ethics.

Conclusion: Finally, it may be concluded from the survey, that respondents have a high level of knowledge, awareness and attitude towards research ethics. However, the research ethics committee should enhance awareness and importance of research ethics among researchers.

Session 4C3

ASSESSMENT OF RESEARCH ETHICS CONCEPTS AMONG POSTGRADUATE STUDENTS

Name: **Abdus Shakoor, Shamim Farhad, ABM Mehedi, Md. Asad Raihan, Md. Abul Kalam Azad, AKM Salek**
Affiliation/Institution: **Bangladesh Bioethics Society, Bangladesh**

Presentation abstract:
A cross-sectional study was performed in The Bangabandhu Sheikh Mujib Medical University (BSMMU), Shahbagh, Dhaka Bangladesh. A total of 200 participants were included in the study to evaluate the concepts on research ethics. A structured questionnaire was given to the respondents to answer the questions. Both dichotomous and nominal-polytomous questions were included in the questionnaire. It was collected properly with the answers of the participants. Chi-Square Test was done for qualitative data. And $p < 0.05$ was considered as the level of significance.
Most of the participants (62.5%) believed that Bangladesh faces many ethical issues in practice. But more male than female participants were in favour of it ($P = 0.05$). Maximum respondents (69.5%) agreed that the primary purpose of a research is to improve good clinical practice. Most of the participants (49.5%) strongly agreed & 41% agreed that ethical review is required for all research involving human subjects. 73.95 % participants have good idea about IC. 2.5 % participants believed that their friends did not take any informed consent. 52% participants agreed, 33% strongly agreed & some (15%) disagreed that all patient has the right to withdraw from the study at any time. Here, more male subjects give favorable opinion about it ($P = 0.04$). Maximum post graduate medical students are knowledgeable on RE but male participants are more conscious about it. But very few of them are not aware of it and could not maintain ethical norms during practice.

Session 4C4

CHALLENGES AND STRATEGIES IN INCULCATING THE IMPORTANCE OF RESEARCH ETHICS IN A MEGA UNIVERSITY IN MALAYSIA

Name: **Abdul Rahman A, Yusof ANM, Md Yusof, Nor-Ashikin MNK**
Affiliation/Institution: **Ethics and Publication Unit, Research Management Centre (RMC), Universiti Teknologi MARA, Malaysia**

Presentation abstract:

Objectives: As a mega university with over 100,000 students and academic staff, our university faces several challenges in ensuring that stakeholders understand the importance of incorporating ethical considerations to produce impactful research. The aim of this experience sharing is to discuss about the issues we experienced as well as our strategies for imparting the value of research ethics in our university.

Method: The issues that we encountered spanned from applicants to reviewers to the research ethics committee (REC) and the secretariat of REC. There is a lack of knowledge to seek ethical clearance before data collection, particularly those from social research programs. From late 2019 through 2021, a series of ethics awareness campaigns have been conducted to address this lack of awareness. These campaigns cover the fundamentals of research ethics as well as an outlined approach to applying for ethical clearance from the university.

Results: The campaigns were a success, with an increase in the number of ethical applications received from 2020 to 2022. However, this triggered other concerns, including inadequate capacity to review most applications, a lengthy review period, and superfluous commentary by the reviewer due to the poor application writeup. The shortage of secretariat personnel in processing thousands of applications is a huge setback that continues to delay the approval process. Hence, the strategies adopted included organizing multiple trainings on how to evaluate ethics approval applications, as well as recruiting more than 200 trained reviewers to strengthen the reviewing process. Speakers from local universities, the National Pharmaceutical Regulatory Agency (NPRA), and from abroad were invited to take part in several sharing sessions. Finally, an online system for ethical approval applications has been developed in collaboration with our university's Information and Communication Technology (ICT) Unit to cater for the overwhelming number of submissions.

Conclusion: Although the initiatives have been tremendously beneficial in overcoming the issues identified, continuous research ethics education is required to ensure the sustainability of an ethical research culture. The importance of secretariat personnel is rarely emphasized, it is crucial to note that efficient secretariat personnel is critical in ensuring all processes are completed in a timely manner to speed research or data collecting. With adequate secretariat staff, the REC could move forward and focus on other aspects such as networking, sharing experiences with other RECs, monitoring ethics approval applications through internal audit, implementing fee charges for clinical trials, and progressing globally in the ethical community network.

Keywords: Ethics awareness, research ethics, teaching and learning, mega-university

Session 5A1

PRINCIPLES OF GOOD IMPLEMENTATION RESEARCH PRACTICE

Name: **Abraham Aseffa**
Affiliation/Institution: **WHO-TDR**

Presentation abstract:

Recent scientific advances have contributed enormously to cure diseases and prevent illness leading to longer life expectancy and better quality of life globally. Research has enabled discovery, development, testing and application of tools such as drugs, vaccines and diagnostics resulting in reduced morbidity and mortality from illnesses through improved health services.

Despite the availability of proven tools and interventions however, morbidity and mortality from preventable and curable diseases continue to persist globally, often emerging as an outbreak among the most vulnerable and marginalized communities. Although, for example, tuberculosis is curable with available drugs, it remains the top killer among infectious diseases. Children continue to die from vaccine preventable illnesses.

Novel products undergo a series of stages of testing using standard scientific methods to ensure safety and efficacy before they are applied in practice. Only a small proportion of the promising novel products in pre-clinical tests make it to and through the stringent randomized clinical trials in humans. The second “valley of death” that products proven to be efficacious and safe in clinical trials have to survive is the successful application in real life conditions.

Implementation research is the systematic approach to understand and address barriers to effective implementation of health interventions, strategies and policies. It addresses the question of for example why proven tools, strategies and interventions fail to make an impact on disease prevalence in particular populations. It seeks solutions against barriers impeding implementation and policy changes. It identifies enablers for maximizing access and impact as well as successful scale up of interventions. It is conducted within real life health systems and communities unlike other types of scientific research which use controlled settings.

The presentation will outline key aspects of implementation research based on the experience of the Special Programme for Research and Training in Tropical Diseases (TDR) whose mission is “to support effective and innovative global health research, through strengthening the research capacity of disease-affected countries and promoting the translation of evidence into interventions that reduce the burden of infectious diseases and build resilience in the most vulnerable populations”.

Session 5A2

GOOD IMPLEMENTATION RESEARCH PRACTICE

Name: **Cristina E. Torres**
Affiliation/Institution: **FERCAP**

Presentation abstract:
Implementation research is a multi-method inquiry that uses both quantitative and qualitative data to plan, assess programs and policies and evaluate interventions. It involves rigorous investigations based on a theory of change conducted in a real world setting. Study participants are real world program actors like health care providers and groups or communities interacting with one another within a specific sphere of activity. The inquiry is done within a specific context where a program, policy or treatment will be/ is being/ or has been implemented. Generally, the investigation is classified into three types: 1) formative research to plan for strategies to be used; 2) process evaluation or trials to test new interventions; 3) impact evaluation towards better future health processes. The research team is often multidisciplinary that is able to use various methods in social sciences, medicine, public health, engineering, etc. to be able to identify the elements of successful intervention strategies. Its value is being able to translate effective and evidence based research findings into life-saving health strategies, health promotion programs and health system approaches that improve health outcomes of the target beneficiaries related to acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability.
The Panel speakers will explain the principles and elements of successful implementation research, discuss the ethical considerations and provide case studies to highlight significant issues that should be addressed.

Session 5A3

GOOD IMPLEMENTATION RESEARCH PRACTICE

Name: **Ng Chirk Jenn**
Affiliation/Institution: **Duke-NUS & SingHealth Polyclinics, Singapore**

Presentation abstract:
Implementation research aims to translate evidence-based health interventions into real-word practice. Ethical issues arise when there is a mismatch between real-world healthcare needs and research priorities; the distinction between the two may not be clear-cut. In addition, implementation research using a hybrid model, where researchers attempt to evaluate both implementation outcomes and intervention effectiveness concurrently, creates tension as pragmatism may supersede scientific rigour.
This paper describes two implementation research projects to illustrate the research ethical challenges faced by researchers throughout the conduct of the studies. The first study was conducted in a primary care setting where a new team-based care model was implemented in response to a national healthcare transformation. The second study involved implementation of a digital application which served as a communication platform between health and social care teams when delivering care for patients with complex needs in the community.

Session 5B1

PROPOSED ABSTRACT TITLE: ETHICAL CONSIDERATIONS FOR MACHINE LEARNING APPLICATIONS IN MEDICINE AND HEALTHCARE – A PERSPECTIVE ON ASSISTING RESEARCHERS AND REVIEWERS

Name: **Hazreen Harith**
Affiliation/Institution: **Universiti Putra Malaysia, Malaysia**

Presentation abstract:

Studies involving artificial intelligence (AI) in medicine and healthcare services introduce significant challenges in ethical review process. AI technologies often involve embedding a machine learning (ML) model to improve the accuracy of a decision-making process. In medicine and healthcare services, these models will eventually impact the patients. Studies submitted for ethical reviews can be of two general types: (i) designing and/or developing the models, and (ii) implementing and/or deploying the models. Model reliability and accuracy, and accountability and liability in implementing AI recommendations are common issues for each respective type.

Two of the main components of ML models include data and algorithms. Until recently, ethical considerations largely focused on patients' privacy and data security due to the need for large data for model development. However, the model development process, which heavily involve data and algorithm, can introduce biases and risks, and affect the end-users. Therefore, it is important that ethical considerations for AI-related studies are assessed comprehensively. WHO emphasizes the following ethical principles and appropriate governance for AI in medicine and healthcare: (1) protect autonomy; (2) promote human well being, human safety, and the public interest; (3) ensure transparency, explainability, and intelligibility; (4) foster responsibility and accountability; (5) ensure inclusiveness and equity; (6) promote AI that is responsive and sustainable. In general, these principles emphasize patients' and carers' benefits. It is postulated that mapping these principles to the ML development and deployment cycle is generally challenging for both reviewers and researchers, thereby affecting the quality of proposals and reviews.

The aim of this presentation is to share the nature of ethical considerations in AI applications in medicine and healthcare submissions to UPM's Ethic Committee (JKEUPM) between 2019 to 2023, and recommend frameworks that may assist future reviews of similar studies. The committee received six applications, with all studies aimed at developing ML models for detection purposes. Four of six studies used images as input data. It is observed that ethical concerns related to data privacy were addressed. On the other hand, the model development and data curation details vary.

The potential risks and benefits of a proposed ML model may not be reviewed comprehensively without sufficient descriptions on data collection, data curation and model development, particularly for reviewers who are not well-versed with ML development and implementation cycle. Similarly, the importance of these details may not be initially obvious for many researchers. Therefore, it is recommended that frameworks which organize ethical concerns according to research type and stages within the ML development and implementation cycle may assist reviewers in providing comprehensive ethical assessment, as well as researchers in incorporating ethical considerations in the proposed ML models early-on. In that way, the eventual benefits of the studies can be maximized over their risks and harms. Currently, three such frameworks include, but not limited to, (i) the Artificial Intelligence in Healthcare Guidelines (AIHGle) co-developed by Singapore's Ministry of Health (MOH), the Health Sciences Authority (HSA) and the Integrated Health Information Systems (IHiS), (ii) the framework proposed by Harini & Guttag, and (iii) the framework proposed by Solanki, Grundy & Hussain.

Session 5B2

INTEGRATING GOOGLE-BASED WORKSPACE AND APPLICATIONS TO THE RESEARCH ETHICS REVIEW PROCESS

Name: **Florabelle G. Taguiling, Jaypee A. Solee, Maria Corazon A. De Ungria**
Affiliation/Institution: **University of the Philippines Diliman, Philippines**

Presentation abstract:
With the increasing push to engage in interdisciplinary multi-site global research, the demand for a fast and efficient ethics review on a borderless online platform pressures Research Ethics Committees (REC) to reduce processing time and find ways to facilitate efficient and researcher-friendly submission processes. In addition, because of the relative novelty of having a protocol for ethical review, some primary researchers may find the submission process difficult because of 1) their lack of familiarity with the protocol, 2) the need for researchers to personally submit multiple physical copies of the protocol and 3) the time-bound nature of physical submission over the online submission.
The University of the Philippines Diliman (UPD) is one of the largest university campuses in the Philippines that boasts diverse research ranging from arts and culture, social sciences, engineering, law, and the natural sciences. This year, UPD finally took on the challenge to seriously establish its own campus-wide institutional Research Ethics Board (UPD REB) under the Office for Research and Development. To address the challenge of physical space, UPD REB immediately adopted a Google-based Workspace to a) streamline the ethics review process, b) ensure the backup of all files by formulating a double backup mechanism for all submitted protocols and c) use a data protection and archiving strategy for all confidential information.
The use of Google-based Workspace and its applications has integrated into streamlining its institutional research ethics review process. It is expected to contribute to the documentation procedures and bridge the gaps between traditional operation methods, including physical reporting a full-on online reporting board operations.
Keywords: Research ethics review process, Google Workspace and Google-based applications, Institutional research ethics board

Session 5B3

A JOURNEY TOWARDS ACHIEVING STRATEGIC SOLUTIONS IN REDUCING TURNAROUND TIME OF PROTOCOL ETHICS REVIEW

Name: **Joshua Jaime P. Nario, Carolyn A. Butler**
Affiliation/Institution: **Makati Medical Center, Philippines**

Presentation abstract:
The Makati Medical Center Institutional Review Board (MMCIRB) has addressed the lengthy approval process of clinical research by improving Turnaround Time (TAT) and overall process. The COVID-19 pandemic also led to the transition to electronic submissions, implementing virtual meetings through the ZOOM platform to support and enable board meetings. In 2014, MMCIRB created the Subcommittee Panels for Investigator-Initiated Research Protocols (SPARES) to review investigator-initiated research protocols. This led to a significant improvement in the turnaround time of approval (TAT). MMCIRB improved its processes through strategic solutions such as the SPARES implementation, document management and departmental communications revision, and the transition to digitalization. Furthermore, MMCIRB implemented quality improvement strategies, including forwarding Weekly Pending Review lists to IRB reviewers every Friday of the week, the IRB Daily Report, and the distribution of submissions of the IRB Secretariat immediately after it has been screened for completeness. The project Process Data Management is currently being developed with the collaboration of MMCIRB and the MMC Information Technology (IT) team. The Risk Assessment or the Functional Failure Mode and Effects Analysis (FFMEA) was conducted, as well as the Strengths, Weaknesses, Opportunities, and Technology (SWOT) and Political, Economic, Sociological, Technological, Legal, and Environment (PESTLE) analyses to identify internal and external factors affecting the system. Moreover, the turnaround time of approval (TAT) is constantly checked as a critical component in the IRB process. SPARES, established in 2014, significantly reduced turnaround time for MMCIRB from 68 days in 2015 to 38 days in 2022, a 56% decrease. Despite doubled protocol volume, SPARES panels delivered decisions quickly, averaging 47-52 days in 2020 and 2021. The Risk Assessment or FFMEA revealed that the steps with the highest Risk Priority Number (RPN) failure modes are 'Data Privacy and Confidentiality' and 'Turnaround time of Approval', prompting MMCIRB to focus on problem prevention and process modifications. The MMCIRB has significantly reduced the time between submission and study approval through digitalization, virtual platforms, encrypted messaging applications, and alternative digital management systems. The pandemic has spurred motivation to improve processes, making it crucial to incorporate technology and embrace innovation to streamline IRB processes. A good data and document management plan considers technical, organizational, structural, legal, ethical, and long-term elements.

Session 5B4

THE EFFECTS OF ELECTRONIC REVIEW ON IRB REVIEW PROCESS

Name: **Tzu-Nien Chen, Yi-Shing Leu, Shih Guan-Jun**
Affiliation/Institution: **MacKay Memorial Hospital, Taipei City, Taiwan**

Presentation abstract:
The Institutional Review Board (IRB) plays a crucial role in protecting the rights, privacy, and welfare of humans participating as subjects in the research. Depending on the type of research, level of risk to participants, the complexity of the study design, and the involvement of vulnerable populations, there are three types of review for an IRB application: Exempt, Expedited, and Full Board Review. Exempt Review typically takes less than a week, while Expedited Review may take up to three weeks, and Full Board Review requires approximately one month or more.

The administrative process of the review includes IRB review and revisions by principal investigators, and it is most commonly criticized for its lengthy duration. Therefore, we would like to understand whether electronic operations can enhance the lengthy IRB review process. Electronic review has been implemented in MacKay Memorial Hospital since 2017. We collected and analyzed the duration of review data at MacKay Memorial Hospital over the past 10 years (2012-2022). We intend to compare the duration between electronic review (after 2017) and non- electronic review (before 2017). The Independent Sample t-test was employed to assess whether the difference between electronic review and non-electronic review is statistically significant. A two-tailed p-value less than 0.05 was considered statistically significant. We used SPSS Statistics version 29.0.1.0 for all statistical analyses.

900 Expedited Review cases before 2017 are compared with 900 Expedited Review cases after 2017. The duration of Expedited Review is shorter with electronic review (average day: 19.7 days; standard deviation: 10.3; $p<0.001$) compared to without electronic review (average day: 29.0 days; standard deviation: 17.6; $p<0.001$). Further analysis of the duration of IRB review for Expedited Review cases, electronic review takes fewer days than non-electronic review (average day:14.3 days; standard deviation:6.9 vs average day:18.8 days; standard deviation:11.4; $p<0.001$). Moreover, the analysis of the duration for principal investigators' revisions in Expedited Review cases also indicates that electronic review takes fewer days than non-electronic review (average day:5.4days; standard deviation:5.5 vs average day:10.2 days; standard deviation:11.3; $p<0.001$).

250 Full Board Review cases before 2017 are compared with 250 Full Board Review cases after 2017. The duration of Full Board Review is shorter with electronic review (average day: 60.0 days; standard deviation: 11.8; $p<0.001$) compared to without electronic review (average day: 72.0 days; standard deviation: 24.6; $p<0.001$). Further analysis of the duration of IRB review for Full Board Review cases, electronic review takes fewer days than non- electronic review (average day:44.8 days; standard deviation:11.7 vs average day:46.2 days; standard deviation:12.3; $p<0.001$). Additionally, the analysis of the duration for principal investigators' revisions in Full Board review indicates that electronic review takes fewer days than non-electronic review (average day:14.8 days; standard deviation:8.4 vs average day:25.8 days; standard deviation:19.1; $p<0.001$). The empirical results demonstrate that the implementation of electronic operations has a significant effect on the review duration of IRB.

Keywords: electronic review, duration, Exempt Review, Full Board Review, IRB application

Session 5C1

CLINICAL TRIALS AND PATIENT'S SAFETY: ISSUES AND CHALLENGES

Name: **Deepa Paturkar**
Affiliation/Institution: **ILS Law College, Pune, India**

Presentation abstract:
Public health encompasses various health issues and challenges across the globe. There are disparities in standards of ethical practices in ensuring public health. Over the years, clinical trials became crucial for gaining new therapeutic approaches to meet the growing expectations of people. Global health and ethical practices across the globe reflect bioethical cross-cutting issues. This research paper aims to explore ethical practices and the law. Three basic ethical principles namely Right, Beneficence and Justice which are at the centre of any clinical trial are one of the ways to achieve this goal. Ethics in Health is based on fundamental values and concepts. In the first part, the paper appraises the codes of ethics and regulations incorporating values and concepts across various jurisdictions while addressing the need for tight regulations with ethical requirements, maintaining high epistemic standards, and balancing the benefits against the risks that are likely to cause harm.

In the new therapeutic approach technology plays an important role. There is continuous update in technology-based scientific research. The recent decade has witnessed tremendous growth in research. However, the nature, behaviour and consequences of patient safety incidents and their surrounding circumstances require urgent attention. Millions of patients worldwide suffer from disabling injuries or death every year due to unsafe medical practices and care. The impact of innovative strategies to address patient safety problems poses new research questions that raise new and unresolved ethical questions. It is undisputed that the Patient's safety is sensitive to ethics which provides and respects sustainable practice where the humanity and dignity of all stakeholders is in question.

The questions of identifying the requirement of the ethical Principle of "beneficence" in case of physician's error, the question of patient's and professional's behaviour while determining the observance of the principle of "respect of persons", role and review of Ethics Committee in the evaluation of strategy in light of the improvement in care are glaring issues emerging in the field.

In the later part, the paper will unleash the main drivers that are identified and formulated in 'the ethical imperative' of patient safety. Underlying values and principles are considered, to increase visibility for the researcher's decision-making. In the concluding part of the paper, the researcher will shed light on gaps in the legal framework and the strategic roles played by the stakeholders in patient's safety will be discussed.

Keywords: Patient's safety, Risk and benefits, Principle of Beneficence, Respect for the person, Global Health and Ethical Practices

Session 5C2

IMPROVING ETHICS REVIEW OF INDUSTRY SPONSORED RESEARCH IN MALAYSIA

Name: **Halimah Mustafa, Sharina Md Nasri, Lee Keng Yee, Asha Tanabalan**
Affiliation/Institution: **Clinical Research Malaysia, Ministry of Health Malaysia, Malaysia**

Presentation abstract:
Ensuring the rigorous and timely ethical review of industry-sponsored research is crucial for upholding participant rights and safety. This abstract delves into the experiences of the Malaysian Research Ethics Committee (MREC) as an Institutional Review Board (IRB) in reviewing clinical trial studies for ethics approval, highlighting its substantial reduction in review time over a five-year period (2018-2022). The involvement of Clinical Research Malaysia (CRM) in supporting MREC's operations and facilitating sponsor, investigator, and authority engagements have also further contributed to this positive transformation.

The data from the past five years demonstrates a significant improvement in the efficiency of ethics review, with the average processing time for clinical trial studies notably decreasing: 2018 (37 days), 2019 (46 days), 2020 (34 days), 2021 (36.58 days), and 2022 (32 days). Despite this accelerated processing, MREC has remained steadfast in its commitment to safeguarding the rights and well-being of research participants.

CRM's support played a crucial role in expediting the review process, by placing two of its employees since 2012 in MREC to help support its operations. These additional resources streamlined administrative tasks, enhanced communication channels, and fostered smoother collaboration between the IRB and sponsors/investigators, ensuring prompt and thorough reviews.

Furthermore, CRM have actively facilitated multiple engagements between sponsors, investigators, and regulatory authorities [National Pharmaceutical Regulatory Agency (NPRA), Medical Device Authority (MDA)]. In providing platforms for valuable discussions between clinical research stakeholders on ethical considerations and regulatory compliance, resulting in improved study designs and heightened participant protection.

In conclusion, the joint effort between MREC and CRM has led to substantial improvement in the ethics review process of industry-sponsored clinical trial studies in Malaysia. The notable reduction in review time is a testament to the commitment of both entities to expedite processes without compromising participant safety and rights. This abstract shows Malaysia's dedication to fostering a robust and ethically sound research environment in the context of industry-sponsored studies.

Session 5C3

ANALYSIS OF SERIOUS ADVERSE EVENTS: REVIEW BY AN INSTITUTIONAL ETHICS COMMITTEE OF A TERTIARY HOSPITAL

Name: **Wong Yin Yen, Chong Lee Ai**
Affiliation/Institution: **SAE Sub-Committee, Universiti Malaya Medical Centre-Medical Research Ethics Committee (UMMC-MREC), Universiti Malaya Medical Centre, Malaysia**

Presentation abstract:

Background and Aim: The Universiti Malaya Medical Centre-Medical Research Ethics Committee (UMMC-MREC) established the Serious Adverse Events (SAE) sub-committee in 2017 to strengthen the monitoring of adverse events and safety of human subjects. Submitted SAE reports are manually entered into a database and reviewed monthly by the SAE sub-committee and reported to UMMC-MREC. Since 2017, there has been several appraisals and improvements made to the reporting processes and the productivity of the SAE committee. This study aims to audit the SAEs submitted to UMMC-MREC.

Methods: This is a retrospective observational study from November 2017 to July 2023. The database of the SAEs was reviewed with permission. The number of SAEs and number of discrete studies were collated monthly and analysed as such. SAE reports were considered late when not received within 2 months of the event. The review process required each SAE report to be categorised as 'No Further Action', "Recommended Action', "Request Information' and 'Pending'. Descriptive analysis was performed.

Results: There were a total 1316 SAE reports and 754 studies during the study period. There was a median of 19 (range 1-51) SAE reports each month. The median monthly SAE in each calendar year has been increasing from 5 (2018) to 25 (2022). There were 125 late reports with an average of 2 per month (range 0-10). There were a total of 80 (median 0, range 0-9) SAE reports that were related to the investigative intervention, resulting in 7 (8.8%) deaths. Of all study participants who died, 76 (91.6%) were unrelated to the investigative intervention. Majority 883 (67.1%) of the reported SAEs required 'No Further Action', 296 (22.5%) required further information from the primary investigator and 130 (9.9%) were pending reports.

Conclusion: While majority of reported SAEs are unrelated to the study intervention, the related SAEs that are deaths are 8.8%. Further training of investigators could reduce late and incomplete reporting. With increasing clinical research studies at our institution, an efficient and technologically-friendly database will be necessary. Limitations of this study are the undetermined number of duplicate reports.

Session 5C4

POST-TRIAL ACCESS- ENIGMA TILL TODAY

Name: **M. Bhattacharjee**
Affiliation/Institution: **Lilavati Hospital & Research Centre, Mumbai, India**

Presentation abstract:

Introduction: In clinical trials, the fate of trial participants on completion of trial still remains a contentious issue. The principles of bioethics include respect for autonomy, beneficence, nonmaleficence and justice. The Declaration of Helsinki (DoH) published in October 2013 in paragraph 34 focused on post-trial access (PTA). The Indian Council of Medical Research (ICMR) guidelines have also put forward the importance of PTA. It may be ethically unfair to stop access to a new drug/intervention that is found beneficial at the end of a trial.

Background: The Council for International Organizations of Medical Sciences 2008 guidelines mention that prior to granting approval to clinical trials, the Ethics Committee should consider available options for PTA. New Drug & Clinical Trial Rules 2019 (NDCT 2019) states “post-trial access” means “making a new drug or investigational new drug available to a trial subject after completion of clinical trial through which the said drug has been found beneficial to the trial subject during clinical trial, for such period as considered necessary by the investigator and the ethics committee.” Though guidelines mention PTA, when it comes to implementation, participants at the end of the trial feel abandoned and exploited.

Problem/Challenges: Several lacunae exist. There is no clarity on who is accountable for PTA- the sponsors, the investigator or the government? PTA should be given for how long, whether to be given to participants only or also to the control group, does it include clinical care /social support besides providing the drug or intervention, who pays for this? How to conduct pharmacovigilance during PTA? What happens once the study drug is licensed-does the patient pay? There are several unanswered questions. Some authors are against PTA citing moral, legal and practical concerns.

Possible solutions: Shared responsibility by all stakeholders (the government, sponsors and researchers) is the way forward in order to guarantee the continuity of treatment for patients, without hindering clinical research especially in resource poor countries. All parties should be aware of individual risks and bounded responsibilities. Policy makers should frame guidelines for possible roll over study or continued and expanded access program to the unregistered investigational product as mentioned in the Multi Regional Clinical Trials document. Workshops to educate ethics committee members, investigators and sponsors on PTA implementation should be encouraged.

Poster 1

RESPONSIBLE CONDUCT OF RESEARCH: ENGAGING A WIDER AUDIENCE IN MALAYSIA

Name: **Rozaida Poh**
Affiliation/Institution: **Universiti Malaya, Malaysia**

Presentation abstract:
\In more recent years, much has been said of the importance of engaging researchers with responsible conduct of research (RCR). What would have been considered the norm research-wise twenty years ago is now gaining understanding to be poor practice, if not outright misconduct. But there is still a lot more that can be done. Despite its importance, RCR is not yet placed as a prerequisite for those planning to get involved or are already involved in research. This apparent sidelining of RCR is true on a global scale, Malaysia included. An initiative on RCR education was spearheaded by the Young Scientist Network-Academy of Science Malaysia (YSN-ASM), executed through various workshops since 2015 on our local scene. Since its inception, the active learning pedagogy had been adopted. In UM, the Master of Health Research Ethics program under Faculty of Medicine offers RCR as a core module. Thus far, four cohorts of graduates for classes of 2019/2020 through 2022/2023 were taught RCR using the active learning pedagogy. Methods included test-learn-test by polling, role-playing, drawing for understanding, case studies, and self-reflection. Assessments were carried out by evaluation of reflective essays following defined rubrics, and quizzes that delineate the best and poor practices, among others. Students have expressed appreciation for the engaging content that the active learning method provided. RCR as a subject matter lends itself very much to the active learning method. Students (or participants for that matter) would have experienced sundry situations throughout their scholarly pursuits in the context of research. When these experiences are drawn out through such learner-centered methods as reflective exercises, students happily realized the importance of RCR.

Poster 2

ASSESSING COVID-19-RELATED STIGMATIZATION IN MALAYSIA'S TRANSITION TO ENDEMIC PHASE: A CROSS-SECTIONAL STUDY

Name: **Leow Mei Lian, Phei Ming Chern, Afham Mohd Muharam, Nur Yasmin Muhammad Fauzi**
Affiliation/Institution: **Clinical Research Centre, Rehabilitation Hospital Cheras, Malaysia**

Presentation abstract:

During the COVID-19 pandemic, Malaysia, like numerous other countries, witnessed a profound impact on global public health. Public health guidelines were established to mitigate the spread of the virus, with lockdowns and restrictions indirectly contributing to public stigmatization and discrimination by increasing fear and anxiety in communities. Moreover, public stigmatization significantly impacts the mental health of affected individuals, subjecting them to stress, anxiety, and depression.

As Malaysia shifts to the endemic phase of the pandemic, this study seeks to assess COVID-19-related public stigmatization, underlining the need for ongoing vigilance in the endemic phase and addressing public stigmatization for the well-being of individuals and society.

Methodology: This cross-sectional research was conducted in Malaysia during the transition to the endemic phase of COVID-19 from 1 February 2023 to 31 September 2023. An online questionnaire distributed through social media platforms, studying the sociodemographic and COVID-19-related public stigmatization using COVID-19 Public Stigma Scale1, a 10-question scale based on 5-point Likert scale to assess public perceptions about COVID-19. The total scores is categorised as: no/minimal (≤18), moderate (19-25) and high (≥26) public stigma towards COVID-19 infection. Data analysis was conducted using IBM SPSS version 26.

Result: There were 396 responses, predominantly aged between 25 and 34 years (40.9%), female (75.8%), Malay ethnicity (63.9%), and with tertiary education (92.7%). Only 3.0% had a history of mental illness. 40.2% reported that both they and their family members had been infected, with 80.1% experiencing home quarantine.

COVID-19 Public Stigma Scale revealed 22.5% respondents with no/minimal stigma, 33.3% with moderate stigma, and 44.2% with high level of stigma towards COVID-19 infection.

Discussion: This study has much lower level of public stigmatization towards COVID-19 infection as compared to the previous study by Ruengorn et al conducted during pandemic which reported significantly higher level of public stigma towards COVID-19 infection (75.8% with moderate to high level of stigma)2.The lower level observed may be contributed by the differences in the timing of the study's conduction, the local pandemic responses, and the variation in public health campaigns and messaging. The lower public stigma level in Malaysia may also be attributed by the success of public health measures and communication strategies, fostering a more informed and empathetic society as the pandemic evolved. Malaysia's highly educated population, as seen in the study, also contributed to this decrease, as educated individuals are more likely to access accurate information, follow guidelines, and show empathy.

Conclusion: The lower level of public stigma towards COVID-19 observed is a promising development of Malaysia transitions the pandemic phase to the endemic phase. It reflects a supportive and empathetic environment during the ongoing health crises. However, it is crucial to maintain the continuous efforts in combating pubic stigmatization towards health conditions which are vital for building a resilient and supportive society that can effectively address any upcoming health challenges in the future.

Poster 3

ETHICAL CONSIDERATIONS IN MENTAL HEALTH LITERACY RESEARCH

Name: **Nasriah Zakaria, Nik Daliana Nik Farid ,Nurul Fazmidar Mohd Noor, Haslina Muhamad**
Affiliation/Institution: **Faculty of Medicine, Universiti Malaya, Malaysia**

Presentation abstract:

Aims: Globally, it is estimated that 10-20% of children and adolescents experience mental health problems such as depression, stress, and anxiety. Mental health problems faced by children and adolescents, if not treated early, will persist to adulthood. Although we are now in the post-COVID 19 period, some patients infected by the covid-19 virus seem to show long COVID symptoms, including depression or anxiety.

A comprehensive digital mental health system to provide mental health status and literacy screening, mental health education and mental health interventions (e-CBT and telepsychiatry) is proposed for the adolescents

- To measure the mental health literacy among adolescents in two cities: Riyadh KSA and Kuala Lumpur Malaysia.
- To design a usable and ethical digital mental health system for adolescents.

Methods: The study will be conducted in the Riyadh and Kuala Lumpur areas as comparable city settings for both countries. Adolescents from the age of 13-17 years in both public and private schools will be eligible for the study. Since adolescents are a minority, we will seek permission from their parents or guardians to be part of the study.

The first phase, adolescents will be answering questionnaires that will measure their mental health literacy (MHL) level. Data cleaning and data analysis will be performed to know the level of mental health literacy.

At the same time, Reusable Learning objects (RLO)will be designed and developed by the team. By definition, reusable learning objects are small learning resources that infuse multimedia elements to stimulate learners (Windle, 2010). Even though it was mainly in higher education settings so that resources can be shared across institutions, RLO can also be used for patient and public education. The RLO will be integrating interactive elements to make learning fun and engaging.

Results: The work in at the development of RLO that fulfil the usable and ethical aspects.

Discussions: Several ethical considerations during the design of digital mental health system which include mental health literacy issue among adolescents, to build mental health resources based on cultural and gender factors, mental health stigma at schools, informed consent from parents, the use Artificial Intelligence to help with psychotherapy.

Conclusion: Building a usable and ethical system in adolescents mental health system must be designed carefully in order to gain acceptance by parents and adolescents.

Poster 4

INDEPENDENT ETHICS COMMITTEE ESTABLISHMENT, GROWTH AND COMMUNITY INVOLVEMENT: PERSPECTIVE FROM A PRIVATE TERTIARY HOSPITAL IN MALAYSIA

Name: **Lam Mynn Dee**
Affiliation/Institution: **Ramsay Sime Darby Healthcare Independent Ethics Committee, Malaysia**

Presentation abstract:

Introduction: Private hospitals worldwide have been progressively exploring active roles in clinical research, encouraging the parallel growth of research ethics committees (EC). Established in 2009, Ramsay Sime Darby Healthcare Independent Ethics Committee (RSDH IEC) stands as a private tertiary hospital ethics committee which is fully registered with the National Pharmaceutical Regulatory Agency of Malaysia. In this narrative poster, we humbly share our perspective in establishing and operating an ethics committee at a leading private tertiary hospital, including its unique challenges.

Methodology: Narrative domains were identified based on literature search and data availability. Next, document review was conducted and relevant data extracted. Narrative domains will include the following: Formal Registration of EC, Considerations and Challenges with Initial Establishment of an Ethics Committee, Scope of Authority, Community Involvement, Appointment Procedures, Inspections and Compliance, and Capacity Building.

Perspectives of a Private Hospital Ethics Committee: The process of formal registration and accreditation for ethics committees is governed by NCCR (National Committee for Clinical Research) and NPRA (National Pharmaceutical Regulatory Agency) and well described in the national guideline. While these guidelines provide a framework, unique considerations emerged during our establishment process. As a private hospital, our operating model and organizational structure may differ from government and public university ECs. Within this distinct context, we established the source and scope of EC authority. RSDH IEC is empowered by the Group Chief Executive Officer and Medical Advisory Board. Besides that, to ensure effective governance of research conduct at our hospital, a robust interdepartmental structure was also established which included the Director, Quality and Risk Management and Clinical Trial Unit. Integration of community representatives and layperson reviewers was written into our IEC member composition policy, thereby ensuring that community involvement is a fundamental and non-negotiable aspect of our ethical review process. Dedicated review forms were also structured to document their perspectives, allowing them to provide valuable input during the evaluation of research proposals. Continuous process improvements have also been undertaken by our ethics committee. The majority of our improvements have focused on refining policy and procedure documents (35%) and optimizing checklist and review forms (18%) over the years. These efforts reflect our unwavering commitment to upholding the standards of ethics in our review.

Conclusion: The establishment of ethics committees in private hospitals presents unique challenges, as they often have distinct organizational structures and cater to specific patient/consumer needs. Adequate institutional support, multilayered effort of the clinical research and quality control team, and sustained commitment of the IEC Chairperson and members have enabled continued growth and development of our ethics committee. Moving forward, our strategy will be to focus on person-centred approach as part of a collaborative and holistic approach to clinical trials.

Poster 5

REVIEW ON ETHICAL GUIDELINES OF PROTOCOL DEVIATIONS IN HEALTH RESEARCH

Name: **Siti Najihah Saidin**
Affiliation/Institution: **Universiti Malaya, Malaysia**

Presentation abstract:
Protocol deviation has been known as protocol violation, protocol noncompliance and protocol variant and it varies to different guidelines and papers that are referred to. Protocol deviations in research studies potentially compromise participant safety and threaten the scientific validity and justification of the study. Therefore, it is of paramount importance to report all deviations to the Institutional Review Board (IRB) to ensure participant safety and maintain research integrity. This study aims to explore the various classifications of protocol deviation in different institutions and within local, regional and international setting, due to many protocol deviation classifications which lead to different monitoring plan by each ethics committee. This analytical paper presents an exhaustive review of the different categories of protocol deviation as specified within existing guidelines, while highlighting the limitations of current practice. The information encapsulated in this paper is gleaned from comprehensive guidelines relating to protocol deviations across various governing bodies. Based on the existing guidelines related to protocol deviations, the variety of classifications and handling methods can potentially cause ambiguity for the audience. Consequently, a set of recommendations has been proposed for the standardization of classification terms and the reporting and assessment timelines for protocol deviations. The prompt and appropriate assessment of protocol deviations is pivotal to ensuring that study participants are not exposed to undue harm.
Keywords: Protocol deviation, protocol violation, classification, non-compliance

Poster 6

ETHICAL CONSIDERATIONS IN CONDUCTING RESEARCH ON VIOLENCE AGAINST WOMEN (VAW)

Name: **Grazele Jenarun**
Affiliation/Institution: **Faculty of Medicine, Universiti Malaya, Malaysia**

Presentation abstract:
Violence against women (VAW) is an act of gender-based violence that results in the physical, sexual, or psychological harm or suffering to women and it is a form of a human rights violation. VAW could have severe impacts on women's health and psychological state, and it also affects the community. In recent years, there has been a substantial number of studies being conducted on VAW. This gives rise to the need for the emphasis of ethical concerns when researching VAW because the women involved may face unethical research conduct and its consequences if inadequate ethical consideration was given. This study aims to explore the views and experiences of the victims who have participated in VAW-related research on ethical issues and to develop a basic ethical checklist in reviewing or conducting VAW research. In this qualitative case study, three women with age range between 31 and 46 years old, having history of VAW and research participation were telephonically interviewed. The findings were divided into types of abuse experienced, effects of the abuse, their experiences and perception on the ethical issues based on the principles of respect for persons, beneficence, non-maleficence, and justice, and how participants felt after participating in the study. The women's openness in research can be influenced by their background and trust towards the researchers which can be developed through community engagement. Research participation also created a sense of justice and empowerment among the women. The information gathered from the interviews and literature review were compiled to construct a simple checklist.
Keywords: Violence against women, Gender-based violence, Domestic violence, Ethics, Research ethics.

Poster 7

ETHICAL CHALLENGES IN MULTIDISCIPLINARY BIOMEDICAL AND SOCIAL SCIENCE RESEARCH AT MU-CIRB, THAILAND

Name: **Rungrapeephan Ujawartee**
Affiliation/Institution: **Center of Ethical Reinforcement for Research, Mahidol University (MU-CERR), Thailand**

Presentation abstract:

Mahidol University Central Institutional Review Board (MU-CIRB), established in 200i8, plays a vital role in reviewing research projects from various departments at Mahidol University, Salaya Campus. MU-CIRB conducts rigorous evaluations of both scientific and ethical aspects of research projects spanning biomedical and social science disciplines, fostering a multidisciplinary research environment. Between 2021 and 2023 (data to September 2ti23), MU-CIRB reviewed 1,210 research projects.

This presentation investigates the comments and concerns raised by MU-CIRB during its reviews, categorized into three primary areas: Ethical Issues, Research Methodology, and Submission Package Completeness.

Ethical Issues encompass concerns related to the clarity of the informed-consent process, the comprehensiveness of participant information sheets, and the language used in these documents. MU-CIRB also examines recruitment materials to ensure they do not inadvertently induce participation.

Research Methodology concerns include the absence of sample-size calculations or insufficient documentation, flaws in research design, inconsistencies between primary outcomes and statistical methods, and the inadvertent inclusion of personally identifiable information in data-collection forms.

Submission Package Completeness is critical and involves issues such as missing or incomplete document attachments, the absence of required signatures from researchers and authorities, and the failure to provide essential permission documents for accessing research sites.

In summary, the recurring comments and concerns identified during MU-CIRB's review of research projects from 2021 to 2023 underscore the importance of thorough preparation before project submission and throughout the research-implementation phase. Adherence to strong research ethics and principles of responsible research conduct enables researchers to make substantial contributions by generating valuable and ethically sound research outcomes that benefit society.

Poster 8

THE “IRB OF RECORD” APPROACH FOR MUL5-FACULTY STUDY REVIEWS AT MAHIDOL UNIVERSITY, THAILAND

Name: **Wunvipa Saengsangiam**
Affiliation/Institution: **Center of Ethical Reinforcement for Research, Mahidol University (MU-CERR), Thailand**

Presentation abstract:
This study presents a pioneering approach to streamline the ethical review process for multi-center and multi-site research studies conducted across diverse departments in Mahidol University, Thailand. The Central Institutional Review Board, Mahidol University (MU-CIRB), is responsible for reviewing research projects initiated by Mahidol departments that do not have their own Institutional Review Boards (IRBs). MU-CIRB has implemented a single-review framework for multi-center studies, known as MU-MOU projects, undertaken across University departments, aiming to enhance the efficiency and flexibility of the review process.
Under this approach, the Principal Investigator's affiliated IRB becomes the Lead IRB or “IRB of Record”. During the review, the IRB of Record extends an invitation to a representative from each collaborating IRBs to join the convened IRB meeting, fostering constructive discussions regarding concerns and areas for project improvement. The Principal Investigator is responsible for all correspondence with the IRBs and submits regular reports using standardized forms. The IRB of Record follows Standard Operating Procedures (SOPs) to evaluate the submission, subsequently sharing pertinent information with the relevant IRBs to facilitate a comprehensive assessment. Acknowledgment leWers are aligned with the IRB of Record's SOP.
Since initiating the IRB of Record concept in 2021, the MU-CIRB has assessed a total of 152 multi-center research projects, comprising 33 Full-Board Reviews, 97 Expedited Reviews, and 22 Exemption Reviews. Serving as the IRB of Record, the MU-CIRB has maintained an average review time of 67 days, notably shorter than the 78 days employed for multi-center studies at Mahidol University between 2018 and 2020.
In conclusion, the adoption of the IRB of Record concept with single-review procedures since 2021 has resulted in a 14.10% reduction in review times, while accommodating a higher volume of multi-center research projects. This streamlined process optimizes researchers' time and resources, ensuring that feedback and concerns are consolidated, minimizing potential confusion and maximizing research
project efficiency.

Poster 9

EMPOWERING RESEARCH ETHICS: MU-CERR'S ROLES AND RESPONSIBILITIES

Name: **Boosaree Titapiwatanakun**
Affiliation/Institution: **Center of Ethical Reinforcement for Research, Mahidol University (MU-CERR), Thailand**

Presentation abstract:
Mahidol University, Thailand, has made significant contributions to high-quality research spanning various disciplines, encompassing health, sciences, the arts, and innovation. Diverse research across these fields is paramount for fostering collaboration and advancing generalizable knowledge. To maintain exceptional quality throughout the research process, it is imperative to ensure research compliance. The Center of Ethical Reinforcement for Research at Mahidol University (MU-CERR) is dedicated to overseeing research compliance practices and enhancing the responsible conduct of research through a range of research-ethics training platforms.

MU-CERR plays a pivotal role in facilitating research compliance involving human and animal subjects, as well as biohazardous agents, through the administration of the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Institutional Biosafety Committee (IBC). As an oversight body, MU-CERR is committed to safeguarding the interests of research-related stakeholders, research subjects, and Mahidol personnel. MU-CERR also actively engages in the processing of Material Transfer Agreements (MTAs) and Data Sharing Agreements (DSAs). MU-CERR actively promotes the awareness of research integrity, translating philosophical ideals into actionable initiatives.

Empowering the protection of human research subjects is of paramount importance in balancing research risks and benefits. MU-CERR's assistance in this regard can be categorized into three key areas: ethical considerations, research methodologies, and submission procedures. First, ethical issues encompass the meticulous examination of informed consent processes and protocol assessments for research involving vulnerable or specific subjects. Second, research methodologies are scrutinized to ensure the production of meaningful results, emphasizing statistical analysis methods (such as sample size calculation) and the scientific underpinnings of the research. Third, MU-CERR provides comprehensive submission forms that align with ethical principles, designed to enable Mahidol researchers to address their ethical concerns promptly via pre-board and post-board forms.

MU-CERR's commitment to empowering research ethics underscores its pivotal role in upholding the highest standards of ethical conduct in research at Mahidol University.

Poster 10

ANALYSIS OF THE KEY POINTS IN THE MANAGEMENT OF ETHICAL TRACKING REVIEW OF CLINICAL RESEARCH

Name: **Lingling Xu**
Affiliation/Institution: **Beijing Tiantan Hospital, China**

Presentation abstract: -

Poster 11

ANALYSIS OF A PITUITARY TUMOR COHORT BASED ON NBTRC

Name: **Hua Gao**
Affiliation/Institution: **Beijing Tiantan Hospital, China**

Presentation abstract: -

Poster 12

ANALYSIS OF A PITUITARY TUMOR COHORT BASED ON NBTRC

Name: **Nur Atik**
Affiliation/Institution: **Department of Biomedical Sciences, Faculty of Medicine, Padjadjaran University, Bandung, Indonesia**

Presentation abstract:
Research in the field of health will continue to evolve as global challenges in solving health issues persist. Health research, including in Indonesia, is inherently intertwined with ethical considerations, particularly in safeguarding the rights and well-being of human participants. To address these ethical concerns and ensure the highest standards of research integrity, Research Ethics Committees (RECs) play a pivotal role in providing ethical oversight for health research involving humans, including reviewing and approving study protocols and monitoring implementation. Ensuring the quality of RECs necessitates accreditation to emphasize their crucial role in maintaining ethical research practices. Moreover, REC accreditation contributes to international harmonization of ethical research standards.
Starting in 2022, the Indonesian Ministry of Health, through KEPPKN (Komite Etik Penelitian dan Pengembangan Kesehatan Nasional / National Health Research and Development Ethics Committee), has initiated the accreditation of RECs in Indonesia. They evaluate six standards, encompassing the structure of the REC, institutional support, standard operating procedures (SOPs), the comprehensiveness of the review process, post-approval review procedures, documentation, and the archieving process within the REC. These standards incorporate international and national guidelines, including SIDCER and FERCAP recognition criteria. It is worth noting that in September 2023, the World Health Organization (WHO) launched a benchmarking tool for assessing the ethics oversight of health-related research involving human participants. This tool encompasses seven categories, from assessing the national context to evaluating RECs and research institutions. While most of the standards for national accreditation in Indonesia already align with the WHO benchmarking tool, there is room for improvement, particularly in providing national guidelines regarding institutional responsibilities in health research.
In conclusion, the tools for national accreditation in Indonesia cover the most critical aspects necessary to ensure the quality of RECs. To further enhance these tools, harmonization with the WHO benchmarking tool is advisable. Another challenge is the effective implementation of the accreditation process, given Indonesia's unique geographical complexities, thus necessitating a regional oversight system.
Keywords: Accreditation, Ethics Committee, Indonesia, Research Ethics Committee, World Health Organization

Poster 13

STATUS OF REGISTRATION AND RE-REGISTRATION AND ACCREDITATION OF ETHICS COMMITTEES IN CDSCO, DHR AND NABH – EVALUATION OF THE EXTENT OF ETHICS OVERSIGHT IN THE COUNTRY

Name: **Ananya Rakshit**
Affiliation/Institution: **Department of Clinical Pharmacology, Seth GS Medical College & KEM Hospital, Parel, Mumbai**

Presentation abstract:

Rationale: The 'New Drugs and Clinical Trials Rules 2019' rule mandates registration of an Ethics Committee (EC) with the Indian regulatory body Central Drug Standard Control Organization (CDSCO) with a five year validity. Ethics Committees (ECs) in medical colleges that oversee Postgraduate theses and academic studies need to be registered with the Department of Health Research (DHR). The present study was carried out with the objective of evaluation of the current status of EC registration, re-registration and accreditation as a metric of ethical oversight in the country.

Methodology: The data from the websites of CDSCO, DHR, Clinical Trials Registry of India (CTRI), National Medical Commission (NMC) and population demographics of states in India was collated. (last accessed - *30th September 2022*). Information of both institutional and independent ECs from CDSCO and DHR were collated as also NABH accreditation. Volume of studies [culled from CTRI] was matched *vis a vis* the number of ECs in a state [and its population]. Both descriptive and inferential statistics [chi square at 5% significance and a crude odds ratio] were applied to the data.

Results: A total of 770 ECs, were initially registered with CDSCO [89% institutional and 11% independent]. Only 295/770 (38.3%) ECs were re-registered with CDSCO. Three seventy medical colleges were recognized by the NMC for post-graduate courses of which only 184/370 (49.72%) had DHR registered ECs. As compared to a previous study, the number of studies registered with CTRI increased from 3689 over a 5 year to 14551 over a 4 year period. However, the number of new EC registration was relatively less (1268 *vs* 770). The average time required for initial registrations of independent ECs decreased from 153 days to 106 days. More ECs were NABH accredited as compared to previous (10% *vs* 7%, not statistically significant).

Conclusion: The registration and re-registration status of ECs as also the accreditation status is not commensurate with the quantum of studies in the country.

Poster 15

CONTINUOUS QUALITY IMPROVEMENT: REDUCING INFORMED CONSENT FORM SIGNING ERRORS

Name: **Tsui-Wen Hsu, Chi-Hung Huang, Li-Ju Chuang, Hui-Chen Lee, Chih-Shung Wong**
Affiliation/Institution: **Cathay General Hospital, Taiwan**

Presentation abstract:

Aims: We used the plan–do–check–act (PDCA) cycle to help improve the correctness and validity of ICF signing.

Methods: This study was divided into two stages. The first stage was before the PDCA intervention, and used for analyzing included 33 clinical trials and 90 PI initiated studies in the control group; 23 clinical trials and 218 PI initiated studies in the PDCA intervention group.

Planning (P). We developed an ICF signature checklist; This checklist emphasized instructions on preventing common errors and correct ICF signing and developing intervention plans.

Intervention (D). First, we implemented a comprehensive approach for ICF signing using a checklist. Second, to enhance clarity and precision, the ICF signature positions were divided and marked with eye-catching red, yellow, and blue signs. Third, we informed the PIs and research teams about the requirement to visit the IRB office to obtain a copy of the approved ICF for reference.

Check (C). We regularly re-educated PIs and research teams and released new regulations to solve existing problems and achieve a higher rate of correct ICF signing.

Continuously follow up (A). Summarized the problems and influencing factors, formulated solutions on the basis of the problems, and the next PDCA cycle was implemented for continuous and systematic improvement.

Results: Our results show that after PDCA intervention, the signature correct significantly increased to 83.3%, and after PDCA intervention, the signature error rate decreased by 11.8%. Signing error type analysis demonstrated significantly fewer signing errors in the post intervention group, in particular, fewer subjects did not add signatures next to the corrections made to the signatures or dates on the ICF (16, 6.7%) and with impersonated signatures (0, 0%; $P < 0.05$).

Discussion: The post intervention group was significantly higher than the pre intervention group, and the PDCA intervention effectively improved quality and reduced ICF signature errors.

Conclusions: We effectively reduced the frequency of ICF signing errors and reduced the rate of ICFs not officially signed after modification and further improved ICF signatures.

Poster 16

THE RELATIONSHIP BETWEEN BURNOUT AND STRESS SCALE OF IRB/REC STAFF

Name: **Po-Hao Chiu**
Affiliation/Institution: **Mackay Memorial Hospital, Taiwan**

Presentation abstract:
According to the law, hospitals and schools had established IRB/REC committees to review studies. IRB/REC staff not only have to review various types of study of different types and degrees of risk , but also to solve every question from PI or sponsor, evaluations, training and even emotional response from PI every day. Hospitals are special workplaces with teams that are formed by many professional healthcare workers. Hospital employees are responsible for looking after the public health. According to the law, every study about humans should be reviewed by IRB/REC. Thus, under the highly working stress causes burnout and turnover rate of IRB/REC staff. For that, one of the evaluation provisions of JCT (Joint Commission of Taiwan): “IRB/REC should have full-time staff and enough finance to handle routine work and at least one who works over two years will be listed as excellent.” Therefore, the supervisory department is aware of the problem in the turnover rate of IRB/REC staff.
Working stress often causes burnout, turnover rate and physical and mental illness. The goal in this study was to know the relationship between burnout and job characteristics of IRB/REC staff. This study used the “Burnout Scale” by Cheng of National Taiwan University and “Stress Scale”. Reviewed by MMH IRB (No. 18MMHIS077e). Data collected time from 2022/10/11 to 2023/06/30. Subjects from the staff of the IRB/REC committee in Taiwan, collected 39 data. The standardized scores of the Burnout levels and the Stress Scale were 42.61 and 6.34. The burnout was not related to the institution's type, gender, title, employment type, age, seniority and weekly work hours but related to the marital status ($P<0.05$). The stress levels were not related to institution type, gender, title, employment type, marital status, seniority and weekly work hours but related to age ($P<0.05$). Scheffe’s method was adopted and the results indicated that stress levels for personnel aged above 50 were higher than personnel aged 35-50 and below 35. Pearson method was adopted and the results indicated that Burnout and Stress Scale were not related.
We found, although IRB/REC staff can handle their job, on highly burnout scales. All items were not related but marital status and age. The average stress score were 6.34% of IRB/REC staff, according to the explanation of Health Promotion Administration (HPA): “In highly stressed status, should go to see the doctor or Mental health professional and receive systemic psychotherapy.” All of the items were not related but age, indicating that the average pressure score of the IRB/REC staff is equivalent. Suggested IRB/REC supervisors can target them to understand working conditions and adjust business content in a timely manner. And can mental health promotion programs such as arranging stress reduction programs to reduce the employee stress index to achieve the WHO health definition: “Health is good for all aspects of physical health, mental health, social adaptation and moral health.”
Keywords: Burnout, Stress Score, Health promotion, Health Promotion Hospital

Poster 17

THE EXPERIENCE TO DEVELOP THE E-IRB SYSTEM OF MACKAY MEMORY HOSPITAL

Name: **Po-Hao Chiu**
Affiliation/Institution: **Mackay Memorial Hospital, Taiwan**

Presentation abstract:
MacKay Memorial Hospital has established the "Human Trial Review Group" since 1993. In 2009, two committees were established: "Institutional Review Board (1)" and "Institutional Review Board (2)". The staff of the secretariat has also evolved from a one-person unit at the beginning of the period to a total of one team leader and four secretaries in order to improve the review efficiency and quality. The work of the secretariats include checking the protocol documents from all institutions of MacKay, members' documents, holding GCP training, handling complaints etc. So, to develop an e-IRB system can reduce the work complexity and increase work efficiency for staff, it also can increase work efficiency for members.
1. Develop motivation:
1.1 Autonomy of system interface design planning and data management rights 1.2 Cooperate with the paperless policy to reduce storage and operating costs 1.3 Improve administrative and review efficiency and improve the submission of continuous reports
2. The experiences and challenges for development the e-IRB
2.1 Communicate with system engineers
2.2 Training for users
2.3 System stability, data backup and information security
3. The planning for the e-IRB system
3.1 Analysis the types of protocols to be a big data
3.2 Automatic output of approval letter
3.3 Automatically output out-link data in series with the "biological information management system of the Association"
3.4 Add the function for "EGC" reviewers and link to IRB protocols
4. Conclusion
Cooperate with paperless policy, review method has gradually changed from "paper review" to "online review". Using and establishment of the e-IRB system is the current trend of IRB review.
To develop the system by itself, in addition to investing a development fee at the
initial stage, IRB colleagues are also required to assist in communication with the development engineer, and the labor cost invested is even more considerable.
However, a "localized" system that fully complies with SOPs can be developed.
Keywords: e-IRB system, paperless, review efficiency

FERCAP-SIDCER ECs/IRBs FOR RECOGNITION IN 2023 (TOTAL: 33)

INDONESIA (6) [2 New]

- Medical and Health Research Ethics Committee (MHREC) Faculty of Medicine, Public Health and Nursing Universitas Gadjah Mada - Dr. Sardjito General Hospital [Yogyakarta | 2012, 2015, 2019, 2023]
- The Ethics Committee of Health Research of Persahabatan Central General Hospital/Komite Etik Penelitian Kesehatan Rumah Sakit Umum Pusat Persahabatan [Jakarta | 2023]
- Health Research Ethics Committee Faculty of Medicine and Health Universitas Muhammadiyah Jakarta [Jakarta| 2023]
- Dental Research Ethics Committee Faculty of Dentistry Universitas Indonesia [Jakarta | 2016, 2019, 2023]
- Health Research Ethics Committee Faculty of Medicine Universitas Indonesia - Dr Cipto Mangunkusumo National General Hospital [Jakarta | 2012, 2016, 2019, 2023]
- Research Ethics Committee Universitas Pembangunan Nasional Veteran Jakarta [Jakarta | 2016, 2019, 2023]

JAPAN (1)

- Nagasaki University Hospital Clinical Research Ethics Committee [Nagasaki | 2015, 2018, 2023]

PHILIPPINES (10) [1 New]

- University of Perpetual Help System-Institutional Ethics Review Board [Las Piñas City, Metro Manila | 2014, 2017, 2023]
- Davao Doctors Hospital Institutional Ethics Review Committee (DDH IERC) [Davao City | 2014, 2017, 2023]
- Bicol Regional Training and Teaching Hospital - Institutional Review Board [Legazpi City, Albay | 2018, 2023]
- Gov. Celestino Gallares Memorial Medical Center (GCGMMC) Institutional Review Board [Tagbilaran City, Bohol | 2023]
- University of Santo Tomas Hospital - Research Ethics Committee (USTH-REC) [Manila | 2015, 2019, 2023]
- West Visayas State University-Unified Research Ethics Review Committee (URERC) [Iloilo City | 2015, 2018, 2023]
- Mary Mediatrix Medical Center - Research Ethics Review Committee [Lipa City, Batangas | 2015, 2018, 2023]
- Single Joint Research Ethics Board (SJREB) [Manila | 2019, 2023]
- Philippine Children's Medical Center Institutional Research-Ethics Committee (PCMC IR-EC) [Quezon City, Metro Manila | 2015, 2020, 2023]
- Cebu Institute of Medicine - Cebu Velez General Hospital Institutional Review Board (CIM-CVGH IRB) [Cebu | 2020, 2023]

FERCAP-SIDCER ECs/IRBs FOR RECOGNITION IN 2023 (TOTAL: 33)

SOUTH KOREA (1)

- Chungnam National University Hospital Institutional Review Board (CNUH-IRB) [Daejeon | 2009, 2012, 2016, 2023]

TAIWAN (2)

- MacKay Memorial Hospital Institutional Review Board [Taipei | 2008, 2011, 2015, 2019, 2023]
- Institutional Review Board of the Cathay General Hospital [Taipei | 2008, 2011, 2015, 2019, 2023]

THAILAND (13) [4 New]

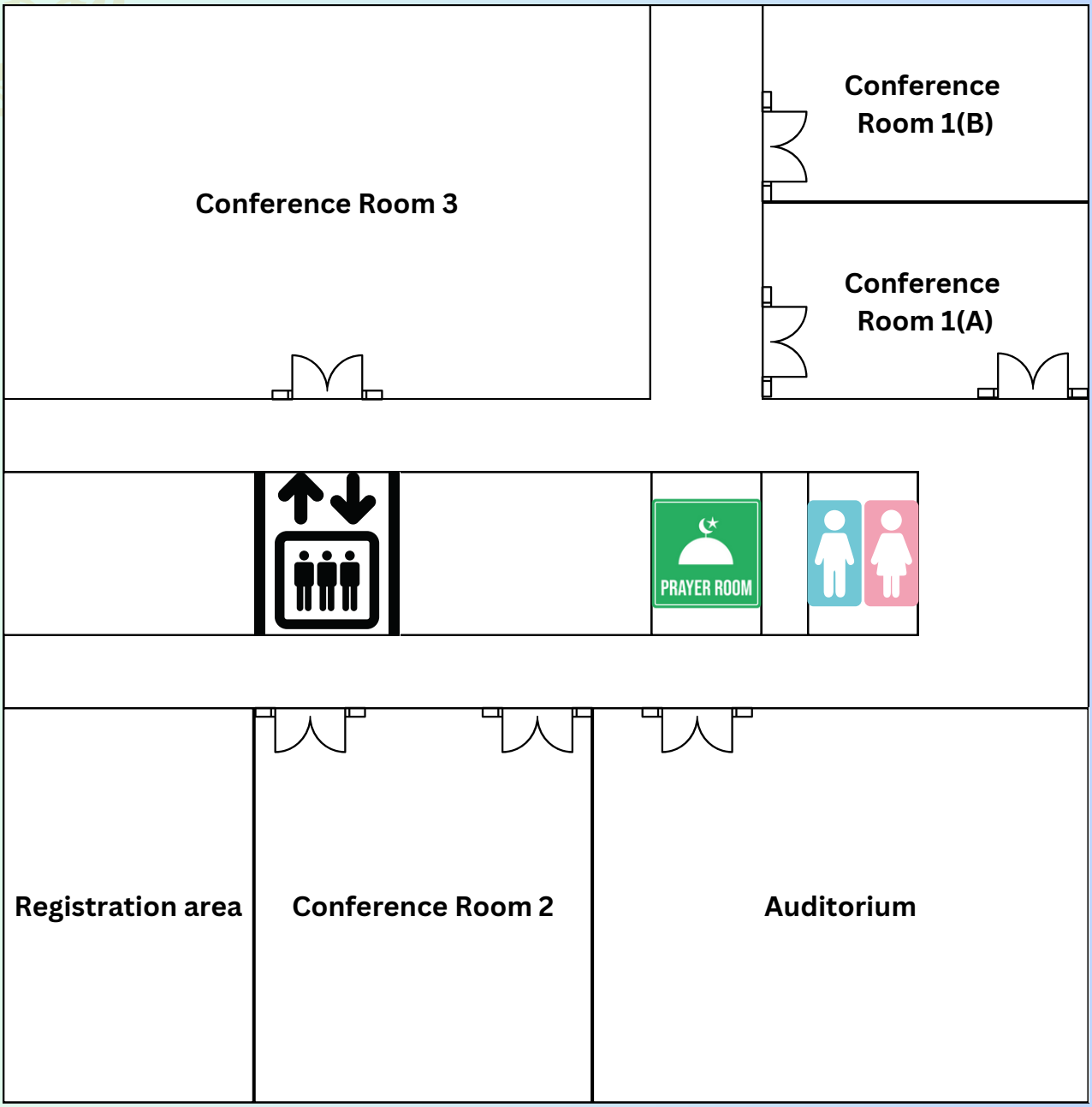
- Human Research Ethics Committee of Ratchaburi Hospital [Ratchaburi | 2023]
- Phetchabun Hospital Independent Ethics Committee [Phetchabun | 2023]
- The Human Research Ethics Committee of Thammasat University (Science) [Rangsit, Pathumthani | 2023]
- Naresuan University Institutional Review Board (NU-IRB) [Phitsanulok | 2013, 2016, 2023]
- Ethical Review Board Boromarajonani College of Nursing, Nopparat Vajira [Bangkok | 2015, 2018, 2023]
- The Ethics Committee for Research in Human Subjects in the Fields of Thai Traditional and Alternative Medicine (TAMEC), Department of Thai Traditional and Alternative Medicine (DTAM), Ministry of Public Health (MOPH) [Nonthaburi |2007, 2010, 2013, 2017, 2023]
- Human Research Ethics Committee of Suranaree University of Technology (HREC-SUT) [Nakorn Ratchasima | 2019, 2023]
- Human Research Ethics Review Committee of Boromarajonani College of Nursing, Bangkok [Bangkok | 2023]
- The Research Ethics Review Committee of Queen Sirikit National Institute of Child Health [Bangkok | 2015, 2018, 2023]
- Burapha University Institutional Review Board (BUU-IRB) [Chonburi | 2019, 2023]
- Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University [Bangkok | 2019, 2023]
- The Khon Kaen University Ethics Committee for Human Research [Khon Kaen | 2008, 2011, 2015, 2019, 2023]
- Research Institute for Health Sciences (RIHES) Human Experimentation Committee, Chiang Mai University [Chiang Mai | 2008, 2011, 2015, 2019, 2023]

PABIN-SIDCER ECs/IRBs FOR RECOGNITION IN 2023 (TOTAL: 3)

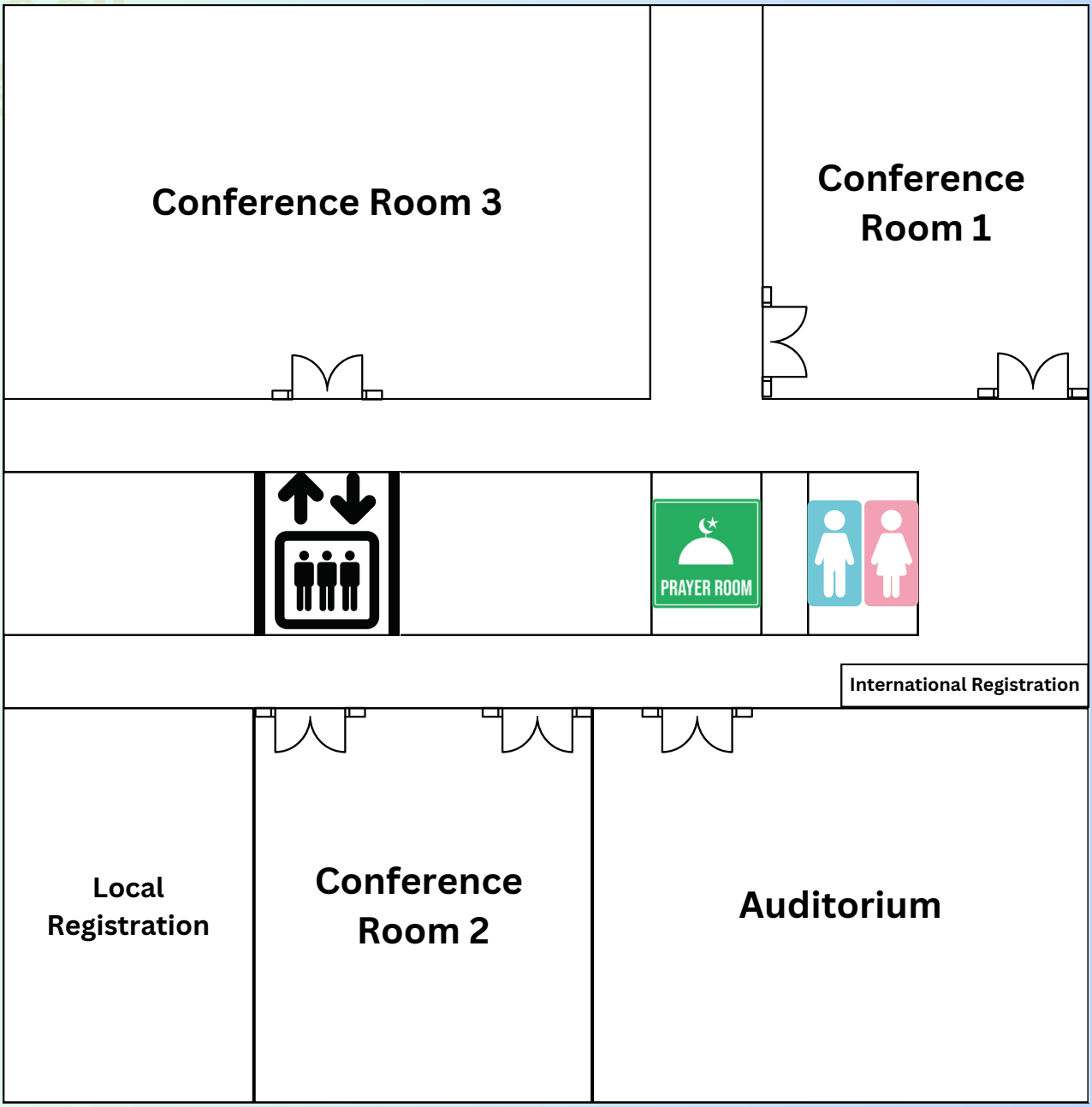
ETHIOPIA (3)

- Institutional Review Board, College of Health Sciences, Addis Ababa University [Addis Ababa | 2009, 2015, 2021, 2023]
- Armauer Hansen Research Institute (AHRI)-All Africa Leprosy Rehabilitation and Training Center (ALERT) Institutional Review Board [Addis Ababa | 2009, 2015, 2019, 2023]
- Ethiopian Public Health Institute (EPHI) Institutional Review Board [Addis Ababa | 2019, 2023]

VENUE LAYOUT



VENUE LAYOUT



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