

22nd FERCAP International CONFERENCE

A hybrid conference with face to face and online participation
November 27-30, 2022
Hosted by Daegu Catholic University Medical Center (DCUMC)
Co-Organized with
K-MEDI Hub: Daegu-Gyeongbuk Medical Innovation Foundation (DGMIF)
KAIRB, Daegu City, DCVB

Theme: Transitioning into the Post Pandemic Era: Ethical Values, Challenges and Approaches

Conference Schedule

| November 27, 2022 | A. Pre-Conference Training (13:00 – 17:00) | |
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| Sunday | Enhancing Lay Participation in Ethics Review of Research | |
| | B. FERCAP Steering Committee Meeting (17:30 – 20:00) | |
| November 28 - 29, 2022 | Conference Proper | |
| Monday – Tuesday | | |
| November 30, 2022 | FERCAP Recognition Program | |
| Wednesday | | |

The global outbreak of the Covid-19 pandemic was a major event in the history of medicine during the 21st century that brought about significant social changes related to individual health, governance systems, drug discovery and regulations, as well as ethical challenges and approaches. The pandemic called for both pharmaceutical and non-pharmaceutical interventions to be done in haste to address contagion. Both high income and low-and-middle income countries were helpless to prevent the onslaught of Covid that caused the loss of lives and large-scale lockdowns that ravaged the economy and the normal lives of ordinary citizens. Emergency use authorization was granted to novel and repurposed medical products to test their efficacy and effectiveness to prevent or treat Covid. Simultaneously public health interventions were adopted that included wearing of masks, physical distancing, travel restrictions to minimize physical contact among the members of the population. All these measures were meant to be implemented with ethical compliance and based on scientific evidence.

With the ebb and flow of the incidence of various Covid variants in different countries at different periods with varying intensity, each country is hopeful that the worst is over, that Covid has become endemic to their locality to enable them to resume their normal lives. During periods of calm when Covid incidence is low, people begin to reconfigure and plan for the post Covid scenario, reflect on their experiences and lessons learned to look forward to better prospects in the future.

The FERCAP conference will seek to describe the unique Covid related experiences and insights related to innovative scientific findings, the ethical challenges and standards that emerged, the new forms of relationships that were formed among various stakeholders to better prepare for future outbreaks and to start rebuilding towards socio-economic growth and better quality of life. It will focus on best practices and ethical solutions in the search for acceptable approaches to difficult challenges posed by the Covid pandemic era and beyond.

PRE - CONFERENCE AGENDA Enhancing the Role of the Lay Person in Ethics Review

November 27, 2022 (13:00 – 17:00)

1300-13:30 The Role of the Laypersons

1330-14:00 The Risk/Benefit Assessment

14:00-14:30 Vulnerability

14:30-15:00 Informed Consent

15:00-15:15 Coffee break

15:15-17:00 Mock IRB

CONFERENCE AGENDA

DAY 1 – NOVEMBER 28, 2022

| 9:00 – 10:00 South Korea time | Opening Ceremony | |
|-------------------------------------|---|--|
| | Session Chair | Kim Jeong Kyu DUMC IRB Executive Chair |
| | Welcome Remarks Congratulatory Messages | Rev. Noh Kwang-Soo President, Daegu Catholic University Medical Center Yang Jin-Young President, K-Medi Hub Chung Jong Woo President, KAIRB Bae Byoung-Jun President, KoNECT Kim Myung Hee President, Korea IRB Accreditation Suh Hun Suk. Head Director, Daegu&Gyeongbuk Reference Lab, Seegene Medical Foundation |
| | Introduction of Guests/Delegation | Kenji Hirayama |

| | | FERCAP Chair | |
|-------------|--|--|--|
| | KEYNOTE Address Promoting Global Health in the Post Covid Era | John Reeder WHO-TDR Director | |
| 10:00-10:15 | Session Break | | |
| 10:15-12:30 | Transitioning from Covid-19 Containment to Normalcy | | |
| Session 1 | Session Chairs: | Vicente Belizario Jr. Vice Chair, FERCAP Chung Jong Woo | |
| | | President, KAIRB | |
| | Advancing Research Ethics Based on Lessons Learned during the Covid Pandemic | Jeremy Sugarman Johns Hopkins Berman Institute of Bioethics, Maryland, USA | |
| | Developing WHO Global Benchmarking Tools for Regulators and Research Ethics Committees | Alireza Khadem Team Lead, Regulatory Systems Strengthening, WHO Geneva Andreas Reis Co-Lead, Health Ethics & Governance Unit, WHO Geneva | |
| | European Code of Conduct for Scientific Integrity | Dirk Lanzerath European Network of Research Ethics Committees (EUREC) | |
| | Korean Initiative towards State-of- the Art Clinical Trials | Kang Ryung Woo KoNECT Director | |
| | Governance of K-Medi Hub and Strategy for Globalization | Jeong Myung Hoon K Medi Hub Secretary General | |
| | Korean Association of IRBs (KAIRB): From the Last 20 Years to the Next 20 Years | Lee Dae Ho KAIRB Secretary General | |
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^{*}to be confirmed

| 12:30- 13:30 | Lunchbreak | | |
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| 13:30-15:00 | Parallel Sessions | | |
| | Ethical Challenges in | Conducting | Sharing Best Practices |
| | Covid Health Care | Educational Activities | among Networks |

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| Breakout Rm. 1 | during the Covid Period Breakout Rm. 2 | Breakout Rm. 3 |
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| Parallel Session 2A | Parallel Session 2B | Parallel Session 2C |
| Session Chair: Fungwei Chang Taiwan Association of IRBs | Session Chair: Kim Yong Jin Chair, Daegu Regional IRB | Session Chair: Lee Sun Ju KAIRB Executive Board |
| Ethical Challenges of Frontline Doctors during Covid-19 Outbreak Abdus Shakoor Bangladesh Medical Society | A Transformative Intervention for Trainers of Research Ethics Education Theingi Thwin et al Myanmar | Round Table Discussion Country and Regional Networks of RECs Participants: President/ Chair of the REC Associations Host: KAIRB |
| Predictive Markers of Covid Mortality in the Emergency Room Kenjie O. Kaiklian, Philippine General Hospital | FERCIT Outreach Adaptive Training during the Covid Pandemic Nithipun Suksumek et al Forum for Ethical Review Committees in Thailand | FERCAP (Dr. Kenji Hirayama) European Network of RECs (Dr. Eugenijus Gefenas) Forum of Indonesian Recognized Research Ethics Committees (Dr. Suryani As'ad) |
| Host Genetic and Epigenetic Factors Affecting Susceptibility and Outcome of Severe Covid Infection LBL Prabodha et al University of Ruhuna, Sri Lanka | Behavior Changes after Online Ethics Training Permyos Ruengsakulrach Bangkok Hospital, Thailand Implementation of a Practicum Program in Research Ethics Phang Kean Chang et al University of Malaya | Forum of Ethical Review Committees in India (FERCI – Dr. Nandini Kumar) Forum of Ethical Review Committees in Thailand (FERCIT – Dr. Suthi) Forum of Ethical Review Committees in Sri Lanka (Dr. Vajira Dissanayake) |
| Ethical and Medical Issues among People | Effectiveness of Research Ethics Training | Network of Ethics Review Committees |

| | with Disability during the Covid-19 Pandemic Taslim Udin et al Sheik Mujib Medical University, Bangladesh | Using the Kirkpatrick Model Nina F. Yanilla et al University of the Philippines Manila | in Malaysia (NERCIM – Dr. Salina Aziz) • Philippine Health Research Ethics Network (PHREN – Dr. Jacinto Blas Mantaring) • Taiwan Association of IRBs (TAIRB – Dr. Fung Wei Chang) |
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| 15:30- 15:45 | Session Break | | |
| 15:45-17:00 | Parallel Sessions | | |
| Session 3 | Participant Perception of Covid-19 and Clinical Interventions | Situation Analysis of Research Ethics Committee Status | Empowering Lay Persons in Ethics Review |
| | Parallel Session 3A | Parallel Session 3B | Parallel Session 3C |
| | Session Chair: Aphornpirom Ketupanya FERCAP (Thailand) | Session Chair: Fung Wei Chang, FERCAP (Taiwan) | Session Chair: Juntra Karbwang SIDCER Coordinator |
| | Factors Motivating Participation in Covid Vaccine Study Dhruve Soni et al King Edward Memorial Hospital Mumbai, India | Exploring Reasons for Non-Existence of Research Ethics Committees Paulo Pagkatipunan et al University of the Philippines Manila | Panel Discussion Interventions to Empower Lay Person Participation in Ethics Review Training Program for Lay Persons in Thailand (Phanthipa Wongwai, Khon Kaen University) |
| | A Discrete Choice Experiment (DCE) to Understand Covid-19 Hesitancy Jeffrey Pradeep Raj et al, King Edward Memorial Hospital Mumbai, India | Situation Analysis of RECs in Bangladesh Shamima Parvin Lasker et al Bangladesh Bioethics Society | Role of Lay Persons in Board Meetings (Dr. David Borasky - WIRB Copernicus IRB) |

| Evaluation of Satisfaction for Participation Covid-19 Clinical Trial Palvi Kudyar, et al King Edward Memorial Hospital Mumbai, India | Ethical Practices among Researchers in Nepal Namita Ghimire et al Nepal Health Research Council | NGO Representative (Ms. Ma. Fatima Lorenzo- Philippines) Lay Person (India) |
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| Knowledge and Perception of Ethics and Clinical Research among Students Suraj K. Tomy et al Seth GS Medical College, | The Role of a Teaching Hospital to Oversee Research Courses during Covid Outbreak Andri MT Lubis Universitas Indonesia | |

17:00- 19:00 Cultural Presentation and Cocktails

| | Day 2: November 29, 2022 | | | |
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| 09:00-10:30 | Parallel Sessions | | | |
| Session 4 | Practices from Research to Policy Addressing Challenges in Ethics Review | | Reviewing Ethical Issues In Covid Research | |
| | Breakout Rm. 1 | Breakout Rm. 2 | Breakout Rm. 3 | |
| | Parallel Session 4A | Parallel Session 4B | Parallel Session 4C | |
| | Session Chair: Dr. Rita Sita Sitorus (University of Indonesia) | Session Chair: Salina Aziz FERCAP (Malaysia) | Session Chair: Cristina E. Torres FERCAP Coordinator | |
| | Balancing Risks and Benefits in Vaccine Trials Ralph Elvi Villabos Philippine General Hospital | Challenges in Ethics Review during the Covid Pandemic Rosliza Abdul Manaf Universiti Putra Malaysia | Round Table Discussion: Ethics Review of Covid Research Diagnostic Tools Clinical Trials for Covid Drugs | |
| | Use of Coaching Video for Broad Consent in Genomic Research Srisintorn W et al | Uncharted Road of Ethics Review of Covid Related Protocols Uma Kulkarni et al | Vaccine Clinical TrialsEffectiveness StudiesCommunityEngagement | |

| | Prince of Songkla University, Thailand | Yenopoya EC, Mangalore, India | |
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| | Analysis of Informed Consent Documents | Challenges in Ethics Review of Covid | |
| | Yash Kamath <i>et al</i> Seth GS Medical College Mumbai, India | Protocols Wilaiwan Chimkhong et al Thammasat University Thailand | |
| | Policy Brief to Disseminate Results of Covid Vaccine Survey Pio Justine Asuncion et al Department of Health Philippines | Assessment of Investigator Queries to Improve REC Performance Varanya Roestpricha et al Thammasat University Thailand | |
| | Ethical Considerations in Clinical Trials in LMICs Ooi Kai Hong University of Malaya | Post Approval Challenges in Ethics Review Aarti Halwai et al YU-FIC, Magalore, | |
| 10:30-11:00 | Session Break | India | |
| 11:00-12:30 | Parallel Sessions | | |
| Session 5 | Perspectives in Clinical Research in the Post Pandemic Period | Public Health Ethics during a Pandemic | Responsible Conduct of Research |
| | Parallel Session 5A | Parallel Session 5B | Parallel Session 5C |
| | Session Chair: Suryani As'ad, Forum of Indonesian Recognized Research Ethics Committees | Session Chair: Jacinto Blas Mantaring III Philippine Health Research Ethics Network | Session Chair: Rosemarie Bernabe University of Oslo |
| | Challenges and Approaches Involved in Pharmaceutical Clinical Trials | Autonomy vs. Paternalism during Covid Outbreak ASM Anwarullah Bhuiyan Bangladesh | Panel Discussion: Responsible Open Science in Europe Project (under the |
| | Yashashri Shetty | 6,3-1 | European Union |

| | Wannarasmi Ketchart Chulalongkorn University, Thailand | Departmer Philip | lichelle de man at of Health pines | Network of RECs Policy Paper on Responsible Open Science |
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| | Risk Factors for Disability after Road Accidents A. Lathaharan Eastern Province, Sri Lanka | Vaccine Co the Pop Xcyllea Departmer | ng Covid nfidence of pulation Abanilla nt of Health pines | Feedback from Research Stakeholders |
| | Critical Factors for Successful Breastfeeding Rolsana R. Ramos Philippine Orthopedic Hospital Ethics Board | Demograph Vaccine C Edlyn J National in Health, Univ Philip Building Di System in I Khondaker Man Banglades | ing the ics of Covid onfidence imenez istitutes of rersity of the ipines gital Health Bangladesh Abdullah Al mun h Bioethics iety | Implications to Research Ethics Review |
| 12:30-13:30 | Lunch Break and Poster Viewing Meeting with National Accreditation System in Various Countries (South Korea, Thailand, Malaysia, Philippines, Taiwan) Host: Kim Myung Hee, President, Korea IRB Accreditation | | | |
| a • = | Addressing Challenges in Session Chairs: | FERCAP Stee ImHee Shin (Nandini Kum | | eering Committee (Korea) |

| Enhancing Lay Person Contribution to Ethics Review | Supatra Porasuphatana/ Juntra Laothavorn, Khon Khaen University/ SIDCER-FERCAP |
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| Protecting Children in Health Research | Bernadette Madrid Ramon Magsaysay Awardee University of the Philippines Manila |
| Innovation and the Asian Clinical Trial Platform | Tatsuo Iiyama Director, Department of International Trials, National Center for Global Health and Medicine, Japan |
| The Role of the University in Preparing for the Next Pandemic | Prasit Watanapa Dean, Faculty of Medicine, Siriraj Hospital, Mahidol University, Thailand David Borasky |
| Promoting a SMART IRB System | WIRB Copernicus IRB, USA |
| Closing Ceremony Invitation to the 2023 FERCAP Conference | University of Malaya |

FERCAP Meeting with Korean IRBs Medical Tour and Dinner (by invitation only)

| FERCAP General Assembly: November 30, 2022 (9:00-12:00) | |
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| Welcome Remarks | Kenji Hirayama |
| | FERCAP Chair |
| Awarding of Certificates of Appreciation | FERCAP Partners in South Korea Daegu Catholic University Medical Center K-Medi Hub Korea Association of IRBs |
| FERCAP Reports | Cristina Torres FERCAP Coordinator Kesara Na Banchang |

| | FERCAP Treasurer |
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| Recognition Ceremony | Juntra Laothavorn |
| | SIDCER Coordinator |
| Best Surveyor Award | Juntra Laothavorn |
| Best Poster Award | SIDCER Coordinator |
| Best REC Award | |
| Closing Remarks | Kenji Hirayama |
| | FERCAP Chair |
| | Arthur Navarro |
| | Master of Ceremony |
| | Jeong Myung Hoon |
| | K Medi Hub Secretary General |

13:00 – 15:00 Medi Hub Invitation for Collaboration in Clinical Innovation Research (by invitation only)