













25th FERCAP International CONFERENCE

A hybrid conference with face to face and online participation November 23-26, 2025 Pre Conference Venue: Siriraj Hospital

Conference Venue: Eastin Grand Hotel, Phayathai Road, Bangkok, Thailand

Theme: Ethics and Quality by Design: Challenges and Opportunities in Research and **Health Practice**

Conference Schedule

| November 23, 2025 | A. Pre-Conference Training (13:00 – 17:00) Siriraj Hospital) |
|--|--|
| Sunday | B. FERCAP Steering Committee Meeting (17:30 – 20:00) |
| November 24 - 25, 2025 Monday – Tuesday | Conference Proper |
| November 26, 2025 | FERCAP General Assembly |
| Wednesday | REC Recognition Program (9:00 to 12:00) |
| | Update FERCAP Surveyor Training on Recent Issues in |
| | Research Ethics (13:00 –16:00) |

PRE - CONFERENCE AGENDA Ethical Considerations in Advanced Genetic Research and Management

Sunday, November 23, 2025 (13:00 – 16:30)

| 13:00-13:15 | Opening/Welcome Remarks | Prof. Naraporn Prayoonwiwat |
|-------------|--|-------------------------------|
| | • | Dean/Deputy Dean for Research |
| | Introduction to Siriraj Institutional | and Innovation |
| | Review Board | |
| 13:15-14:00 | Establishment of "Genomics Thailand | |
| | Project": Ethical and Operational Issues | Prof. Manop Pitakpakorn |
| 14:00-14:40 | Ethical Considerations in Advance | Prof. Duangrurdee |
| | Therapy Medicinal Product (ATMP) in | Wattanasirichaigoon |
| | Adults and Children | Dr. Chanin Limwongse |
| 14:40-14:50 | Session Break | |
| 14:50-15:20 | Research in Stem Cell Therapy: | Asso. Prof. Weerapat |
| | Scientific and Ethical Issues | Owattanapanich |
| | | |
| 15:20-15:50 | Ethical Guidance for Human Genome | Prof. Chairat Chayakul |
| | Data | 1 101. Chanat Chayakui |
| | Collection, Access, Use and Sharing | |
| 15:50-16:00 | Q & A | |

| | Additional Activities at Siriraj Hospital | | |
|--------|--|--|--|
| | <u>Sunday, November 23, 2025 (10:00 – 12:00)</u> | | |
| 10:00- | Option 1: | | |
| 12: 00 | Guided-tour of Siriraj Medical Museum and Siriraj Bimukstan Museum | | |
| | Duration 2 hours; BHT 700 (USD 20); maximum 100 persons | | |
| | Option 2: | | |
| | Thai traditional massage; Siriraj Sappaya-sthana, 7th floor, Siriraj | | |
| | Piyamaharajkarun Hospital, | | |
| | Duration 1 hour; BHT 1,400 (USD 50) | | |

CONFERENCE AGENDA DAY 1 – NOVEMBER 24, 2025 8:30 - 9:30**Opening Ceremony Bangkok** Time Session Dr. Kenji Hirayama, FERCAP Chair Chairs **Welcome Remarks** Permanent Secretary of Ministry of Public Health **Introduction of Guests of Honor** Juntra Laothavorn **Introduction of Country Delegates** Dr. Kenji Hirayama **FERCAP Chair KEYNOTE Address Establishing a collaborative network** Director among research stakeholders towards Health Systems Research quality clinical research Institution, Thailand Ministry of Public Health **Strengthening partnership between** science and ethics towards better WHO-TDR Director General global research utilization 9:30-10:00 **Session Break Plenary Session** 10:00-12:00 Ethics and Quality by Design in Health Research and Practice Session 1 **Session Chairs:** Juntra Laothavorn SIDCER-FERCAP President 1. Using Good Empirical Research in Research Jeremy Sugarman **Ethics in Improving Current Practices** Johns Hopkins University, USA Rohit Malpani Benefits and Risks of AI Technology in 2. WHO Consultant Drug Development and Delivery 3. Strengthening Capacity of Regulators for Director **Quality Research** Pharmaceutical and Medical Devices Agency, Japan Program Innovation and Management in **Michael Mihut** 4. Health Research WHO TDR Officer Stakeholder Roles in Promoting Verity EU Funded Project 5 Scientific Findings and Information Project Representative Perspectives towards Participant- Centric Cristina E. Torres 6. **FERCAP Coordinator** Health Research 12:00-13:00 Lunchbreak **Parallel Sessions** 13:00-14:30

| Session 2 | Addressing Quality Issues in Ethics Review | Educating and Training Research | Use of Technology in Health Research |
|-------------|---|---|---|
| | Session 2 A | Stakeholders Sesssion 2B | Session 2C |
| | Hall A | Hall B | Hall C |
| | | | |
| | a. Navigating Complexity | a. Capacity Building | a. A Comparative Analysis |
| | in International Collaborative Research | through the Southeast Asian Casebook on | of AI Regulatory Guidelines in Clinical |
| | and Quality by Design | Health Research Ethics | Research. |
| | among RECs Keiichiro | Nishakanthi Gopalan et al. | Uthara H Iyer |
| | Yamamoto, Japan | Universiti Malaya (UM), | IRB Tata Memorial |
| | Institute for Health | Malaysia. | Hospital, Mumbai, India |
| | Security, Japan yamamoto.kei@jihs.go.jp | nisha.gopalan@um.edu.my | iyeruthara@gmail.com |
| | | b.Female community | b. From Policy to Practice: |
| | b. Analysis of Minutes of Subject Expert | healthcare volunteers' | Guiding IRB Users through Conversational |
| | Committee (SEC) | engagement in promoting rational antimicrobials | Generative AI. |
| | Meetings during | use. Nisha Jha et al. KIST | Chien-Liang Ho National |
| | COVID. Anjali Shah, | Medical College and | Cheng Kung University |
| | Seth GS Medical College | Teaching Hospital, Nepal | Hospital, Taiwan |
| | and KEM Hospital, India anjalishah1659@gmail.com | nishajha32@gmail.com | hocl@mail.ncku.edu.tw |
| | | c. Multi-Modal Outreach | c. Analysis of Key Points for |
| | c. Embedding Community | Initiatives of the Thai | Ethical Review in Clinical |
| | Engagement in Research | Royal Army IRB. | Research on Artificial Intelligence. |
| | with Vulnerable Populations. Rumana | Nithipun Suksumek et al. Royal Thai Army, Thailand | Xiao Shuping et al. Beijing |
| | Akhter Saifi, Faculty of | drnithipun@hotmail.com | Tiantan Hospital, China |
| | Medicine, Universiti | | ttyyirb@163.com |
| | Malay | d.Effect of Research | |
| | arumana@um.edu.my | Education on Clinical | d.Ethical Considerations in Research on the Use of |
| | d Challanges of Ethical | Trial Engagement: A Gender-Based Analysis | Artificial Intelligence in |
| | d. Challenges of Ethical Review in Patient- | from Taiwan. | Diagnosis of Infectious |
| | Centered Clinical Trials. | Tsui-Wen Hsu, Cathay | Diseases. |
| | Yue Xiaolin, Beijing | General Hospital, Taipei, | Vicente Belizario Jr. et al. |
| | Tiantan Hospital, China | Taiwan <u>irb@cgh.org.tw</u> | NIH, UP Manila vybelizario@up.edu.ph |
| | ttyyirb@163.com | e. Training Program for | |
| | e. An Ambispective Study | Office Staff Supporting | e. Cross-tool Evaluation of |
| | to Investigate the | the Operations of | AI Drafted Informed |
| | Common Errors in Oncology Research | Research Ethics Committees Samaporn | Consent Documents. Shama U Rao et al. |
| | Submissions Bhavesh | Prommasakha Na | Centre for Ethics |
| | Bandekar, Tata Memorial | Sakonnakhorn, Khon Kaen | Yenepoya, Mangalore, |
| | Centre, Homi Bhabha | University, Thailand | Karnataka, India |
| | National Institute, | samaporn@kku.ac.th | shamaurao@ymail.com |
| | Varanasi, India | | |
| | bhavesh.bandekar1988@gma il.com | | |
| 14:30-15:00 | | Session Break | |
| | | | |

| 15:00-16:30 | Societal Perspectives in | Fostering Good REC | Special Topics in |
|-------------|------------------------------------|--|--|
| Session 3 | Research | Procedures | Health Ethics |
| | Session 3A | Session 3B | Session 3C |
| | a. Toward a Relational | a. Next-Gen IRB: | a. The Ethical Use of |
| | Ethics of Mental Health | Integrating Technology | Human Cadavers in |
| | Inspired by Immanuel | for Ethical Excellence. | Health Research. |
| | Levinas and Martin | Chien-Liang Ho National | Veeranarasimman |
| | Buber Jose Alvaro A. | Cheng Kung University | Ravendran. MOHRE |
| | Adizon University of the | Hospital, Taiwan | University Malaya |
| | Philippines Diliman, | hocl@mail.ncku.edu.tw | 22088637@siswa.um.edu.my |
| | Philippines | h Eastana Influencing the | |
| | jaadizon@up.edu.ph | b. Factors Influencing the Efficiency of Human | b. Ethical Stewardship and |
| | b. Reviewing Related | Research Ethics | Pre-Consent in |
| | Methodologies for | Administration Daranee | Biological Collection in Genomics |
| | Ethical Research with | Khamsawat, Suranaree | Maria Corazon A. De |
| | Indigenous Peoples | University, Thailand | Ungria et al. University of |
| | Florabelle G.Taguiling et | daranee@g.sut.ac.th | the Philippines Diliman, |
| | al., University of the | | Philippines Philippines |
| | Philippines, Diliman, | c. Accelerating IRB | madeungria@up.edu.ph |
| | fgtaguiling@up.edu.ph | Minute-Taking with an | |
| | | AI-Enabled Workflow. | c. Guidance for Research |
| | c. Mitigating Medical | Tsang-Tang Hsieh et al., | Ethics and Research |
| | Misinformation and | Taiwan Chang Gung | Integrity in Using |
| | Disinformation | Medical Foundation | Human |
| | Ilene Wilets, Icahn School | (CGMF) tth3388@gmail.com | Biospecimens. |
| | of Medicine at Mount | tui5388@gman.com | Aye Aye Khin et al. |
| | Sinai. | d. Boilerplate Language | Department of Medical Research, Myanmar |
| | ilene.wilets@mssm.edu | and Protocol-Consent | directorgeneralayeayekhin@ |
| | d. Ethical Practices in | Misalignment in | gmail.com |
| | Applied Linguistics | Informed Consent | |
| | Research with | Forms Nattharmma | d. Evolving Trends in |
| | Individuals with | Namfah et al. Burapha | Environmental Research |
| | Tourette Syndrome. | University, Thailand | Namita Ghimire & |
| | Aileen B. Del Rosario De | nattharmma.th@go.buu.ac.th | Pramod Joshi, Nepal |
| | La Salle University, | a Davelanment of | Health Research Council |
| | Manila, | e. Development of | meetnamitag@gmail.com |
| | Philippines <u>aileen.bautista</u> | Database and Dashboard for | |
| | @dlsu.edu.ph | Monitoring Operations | e. A Retrospective Analysis |
| | e. Exploring Disparities in | of an IRB Patcharaporn | of the IRB Decisions on |
| | Human Dignity and | Sudchada, Naresuan | Oral Health. |
| | Justice on the Tribal | University, Thailand | Wen Lin Chai. Faculty of Dentistry, Universiti |
| | Communities during | patcharaporns@nu.ac.th | Malaya, Malaysia |
| | Climate Change, Josna | A G B | chaiwl@um.edu.my |
| | John BR, Fogarty | f. Common Reasons for | |
| | Program, Yenopoya | Ethics Committee | f. Navigating Ethical |
| | University, India | Disapproval of Industry- | Challenges in First-in- |
| | dr.josnavinod@gmail.com | Sponsored Clinical Trial Applications. | Human (FIH) Trials: |
| | | Halimah Binti Mustafa, | Swee-Ping Tang et al. |
| | f. Ensuring Credibility in | Ministry of Health | Medical Research Ethical |
| | Qualitative Research | Malaysia Malaysia | Committee, Ministry of |
| | Prakash C. Bhattarai, | halimah.nih@gmail.com | Health Malaysia |
| | Kathmandu University Nepal | | tangsweeping@gmail.com |
| | Тусраг | | |
| 17:00-20:00 | Welcome Dinn | er and Individual Countr | v Presentation |
| 17.00-20.00 | Welcome Dim | ici anu murriuuai Counti | j i i cocination |
| | | | |

| | Day 2 – November 25, 2025 | | |
|--------------------------------|---|--|--|
| | Parallel Sessions | | |
| 8:30- 10:00 Session 4 | Preparing for the Next Pandemic Session 4A | Vulnerability and Consent in Research Session 4B | Ethical Issues in Initial Review of Health Research Session 4C |
| 10:00- | a. PREPARED: How to conduct research ethically and with integrity during pandemics. Doris Schroeder et al. University of Lancashire, UK DSchroeder@lancashire.ac.uk b. Ethical challenges of pharmacological repurposing and scientific responsibility during the COVID-19 pandemic. Carmine Iorio, University of Perugia, Italy carmine.iorio@dottorandi.unipg it. c. Funding and function during crises: a global survey of research ethics committees during the COVID-19 pandemic. Carly Seedall (European Network of Research Ethics Committees: EUREC) Carly@EURECOffice.onmicros oft.com d. Determinants of COVID-19 Vaccine Hesitancy among Senior Citizens Jonah Christi Miñoza-Ancog, MD, CFP Governor Celestino Gallares Memorial Medical Center, Philippines jonahchristi@gmail.com e. Gaps in the regulatory framework for clinical trials in Africa Renatha Kato Tanzania renatha.kato@nimr.or.tz | a. Ethical Considerations in Malaria Vaccine Trial among the Indonesian Military Population Fuad Alhadi, Oxford University Clinical Research Unit, Indonesia falhadi@oucru.org b. Researching Disaster Nursing Competency Junaliza Cunado et al Governor Celestino Gallares Memorial Medical Center, Bohol, Philippines sarigumbamvp@gmail.com c. Whose Genome is it Anyway? Ethical and Regulatory Complexities in International Data Sharing. Alex Phang Kean Chang, Universiti Malaya drphang@um.edu.my d. Social behavioral study protocol and vulnerability from an ethics committee perspective Maliwan Oofuvong, Faculty of Medicine, Songkhla, Thailand oomaliwa@gmail.com e. Vulnerability during Climate Change Events. Abdus Shakoor, Bangladesh Medical University, Dhaka, Bangladesh shakoorma@bsmmu.edu.bd | a. Evaluation of reasons for participation in a clinical trial among patients in the outpatient department. Gajbhiye SV et al., All India Institute of Medical Science, Nagpur, India dr.ssborkar@gmail.com b. Ethics and Participant Recruitment in Clinical Research. Pura R. Caisip. Cardinal Santos Medical Center. puracaisip@yahoo.com c. Management and Practice of Exemption from Informed Consent Review Bai Caizhen et al. Beijing Tiantan Hospital, China baicz04@163.com d. A Comprehensive Evaluation of Expedited Protocols at a Tertiary Oncology Centre Kasturi Awatagiri, Advanced Centre for Treatment, Research and Education in Cancer TMC Kharghar, Navi Mumbai, INDIA kawatagiri@actrec.gov.in e. Ethical Review of Decentralized Clinical Trials. Liang Xiaoshan et al Beijing Tiantan Hospital, China Liangxiaoshan127@126.com |
| 10:30 | | Session Dieak | |

| 10:30- 12:00 Session 5 | | Ethical Issues in Community Research and Engagement Session 5A | | Ethical Research in Clinical Care Session 5B | R | EC Monitoring of Clinical Trials Session 5C |
|---------------------------------|----------|--|----|--|----------|--|
| | a. b. | Fostering Societal Trust in Science Lisa Haberlain et al., European RECs, Germany haeberlein@eurecnet.eu A Survey on Open Science Perceptions and | a. | Assessment of medication safety in a tertiary care teaching hospital Anjula Palikhe, KIST Medical College and Teaching Hospital, Kathmandu, Nepal palikheanj@gmail.com | a. | Post-approval monitoring: compliance with regular research site visits Samaporn Prommasakha Na Sakonnakhorn, Khon Kaen University, Thailand samaporn@kku.ac.th |
| | | Experiences among One Health researchers in South Asia Naheeda Hamza et al., University of Oslo, Norway naheeda.hamza@studmed.uio.no Influenza Vaccine | b. | Treatment Adherence among Patients with Pulmonary TB Michelle Antinette Yap et al. University of Bohol, Philippines sarigumbamvp@gmail.com | b. | Outcomes of clinical trial site monitoring by an Ethics Committee Chaitali Ashish Chindhalore All India Institute of Medical Sciences, Nagpur, India drchaitali@aiimsnagpur.edu.in |
| | c. | Hesitancy: A Discrete Choice Experiment on Public Preferences and Ethical Trade-Offs. Jeffrey Pradeep Raj. Kasturba Medical College Manipal, India jpraj.m07@gmail.com | c. | Out-of-Range Methotrexate Levels and the Ethics of Monitoring In-patients with Malignancy Nitisha Baruah, Kasturba Medical College Manipal, India nitisha.kmcmpl2024@learner.ma | c. d. | A Retrospective Review of Site Visit Reports by the Ethics Committee. Edwin C. Ruamero, Jr et al. University of the Philippines Manila- College of Pharmacy ecruamerol@up.edu.ph A retrospective audit to |
| | d. | A Reassessment of Indigenous Community and Joint Authorship Practices Lakan Uhay D. Alegre University of the Philippines Diliman ldalegre@up.edu.ph | d. | Ethical and Economic Implications of Cancer Chemotherapy Drug Wastage Mohamed Siddiq Muhammad Basheer Kasturba Medical | u. | analyse protocol deviations in regulatory clinical trials at a single centre in India. Roopa Parida, M. Seth GS Medical College & King Edward Memorial Hospital, Mumbai, India dr.roopaparida@gmail.com |
| | e. | Social Participation Index Related to Health Status of Senior Citizens. Ryan Jerico et al., University of Bohol, Philippines sarigumbamvp@gmail.com | e. | College Manipal, India siddiq.kmcmpl2023@learner.man ipal.edu Ethical Perspectives on Genetic Data Reuse among REC Members Revanasiddappa Devarinti et al. KLE Academy of Higher Education and Research, India kleclinicalresearch@gmail.com Knowledge, Perception, and Use of Generic Medication Kevin Louise Fudalan et al. University of Bohol, | e. | Signal Detection of Gastrointestinal and Pulmonary Adverse Events in Inhaled Antibiotic Therapy for Cystic Fibrosis Balamurali Krishna. KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Belagavi and Kasturba Medical College, India bmk11095@gmail.com |
| | | | | Philippines sarigumbamvp@gmail.com | | |

| 13:00- 14:30 Session 6A Benefit Sharing and Post Trial Arrangements Session 6A Session 6A Session 6A Session 6B | 12:00- 13:00 | Lunch Break | | | | |
|--|----------------------------|--|---|--|--|--|
| Systematic Literature Review a. A scoping review of PTA during the Ebola epidemic. Bendkhale SR and Sawant NS. Seth SS Medical College, India bendkhale s@gmail.com b. PTA in Social Media and Grey Literature, Xcellea Jasmine Abanilla et al Department of Health, Philippines seabanilla@doh.gov.ph Regulator Perspectives a. Insights from Brazilian Regulators Fernando Hellmann, Federal University of Santa Catarina (UFSC) Brazil hellmann.fernando@gmail.com b. Preception of Nepal Regulators, Prem Lai Basel, Institute of Medicine, Nepal prembasel 11@gmail.com c. PTA Covid Regulations in the Philippines. Pio Justin V. Asuncion et al., Department of Health, Philippines pusumcion@doh.gov.ph Sponsor Perspectives PTA Perception and Practices of Sponsors, Nithya Gogtay, Seth GS Medical College Mumbai, India njgogtay@hotmail.com REC Perspectives REC Perspectives a. REC Review of PTA in 6 Countries, Malekia S.E et al., National Institute for Medical Research, Dar es Salaam, Tanzania Tanzania Tanzania the Basel Institute of Medician Research on Nutraceuticals for Breast Cancer ARISE Network for Infectic Diseases Memira T. Daguman University of Santa Comas, Philippines publication of Salmira Agaguman gs@ust.edu.ph Addressing Ethical issues in Trituration Process of Ayurvetic Medician College, Kolkota, West Bengal, India. dr seduta@vahoo.co.in C. A Multidisciplinary Approach in the Perioperative Manangement of Large Mana | 13:00- 14:30 Session | Trial Arrangements | Biomedical Research | | | |
| b. REC Perception of PTA in Kenya, Beatrice Amugune, University of Nairobi, Kenya beatrice.amugune@uonbi.ac.ke | | a. A scoping review of PTA during the Ebola epidemic. Bendkhale SR and Sawant NS. Seth GS Medical College, India bendkhale.s@gmail.com b. PTA in Social Media and Grey Literature, Xcellea Jasmine Abanilla et al Department of Health, Philippines xeabanilla@doh.gov.ph Regulator Perspectives a. Insights from Brazilian Regulators Fernando Hellmann, Federal University of Santa Catarina (UFSC) Brazil hellmann.fernando@gmail.com b. Perception of Nepal Regulators, Prem Lai Basel, Institute of Medicine, Nepal prembasel11@gmail.com c. PTA Covid Regulations in the Philippines. Pio Justin V. Asuncion et al., Department of Health, Philippines pvasuncion@doh.gov.ph Sponsor Perspectives ✓ PTA Perception and Practices of Sponsors, Nithya Gogtay, Seth GS Medical College Mumbai, India njgogtay@hotmail.com REC Perspectives a. REC Review of PTA in 6 Countries, Malekia S.E et al., National Institute for Medical Research, Dar es Salaam, Tanzania sia.malekia@nimr.or.tz b. REC Perception of PTA in Kenya, Beatrice Amugune, University of Nairobi, Kenya | the Early Phase Type 2 Diabetes Mellitus. Almira T. Daguman University of Santo Tomas, Philippines almira.daguman.gs@ust.edu.ph b. Addressing Ethical issues in Trituration Process of Ayurvedic Medicine Subhas Chandra Dutta J B Roy State Ayurvedic Medical College, Kolkota, West Bengal, India. dr scdutta@yahoo.co.in c. A Multidisciplinary Approach in the Perioperative Manangement of Large Merkel Cell Carcinoma Jagdeep Sharma, HBCH & RC, New Chandigarh & HBCH, Sangrur, India Sharmaj@hbchrcm.tmc.gov d. Patient and Public Involvement in Clinical Research on Nutraceuticals for Breast Cancer Abdullah Yahya Ebrahim Zaawari, Kasturba Medical College Manipal abdullahalzawari.aa@gmail.co m e. Biospecimen Donation for Biomedical Research and New Drug Development Madhanakumar MP. Kasturba Medical College Manipal, India | | | |

| 14:30- | Plenary Session | | |
|-----------|---|--|--|
| 15:00 | Quality by Design: Implementing ICH-GCP R3 (2025) | | |
| 15:00- | ✓ Role of Regulator | | |
| 17:00 | ✓ Role of Pharmaceutical Sponsor | | |
| Session 7 | ✓ Role of Contract Research Organization | | |
| | ✓ Role of Research Ethics Committee | | |
| | ✓ Risk-Based Approaches | | |
| | ✓ Use of Real World Evidence | | |
| | ✓ Decentralized Clinical Trials | | |
| | Closing Ceremony | | |
| | Announcement of 2026 FERCAP Conference in Makassar, Indonesia | | |

| FERCAP General Assembly: November 26, 2025 (9:00-12:00) | | |
|---|--|--|
| Welcome Remarks | Kenji Hirayama FERCAP Chair | |
| Exploring Collaboration between EUREC and FERCAP | EUREC Chair | |
| Strengthening Collaboration between Thailand and FERCAP | Thai Representative | |
| Awarding of Certificates of Appreciation | FERCAP Conference Partners in Thailand | |
| FERCAP Reports | Cristina Torres FERCAP Coordinator Kesara Na Banchang FERCAP Treasurer | |
| Recognition Ceremony | Juntra Laothavorn SIDCER Coordinator | |
| Accomplishment Awards | Juntra Laothavorn SIDCER-FERCAP President | |
| Closing Remarks | Kenji Hirayama FERCAP Chair | |

| Update FERCAP Surveyor Training on Challenges and Initiatives in Ethics Review (13:00 –16:00) | |
|---|----------------------|
| Challenges and Opportunities in Research Ethics Review | FERCAP Training Team |
| Reviewing REC Implementation of Updated International Guidelines | |