



SIDCER
Globalizing Ethics for Health Research



24th FERCAP International CONFERENCE

A hybrid conference with face to face and online participation

November 24-27, 2024

Hosted by Nepal Health Research Council

Everest Hotel, Kathmandu, Nepal

Theme: Maximizing Benefits through Responsible Conduct of Research

Conference Schedule

November 24, 2024 Sunday	A. Pre-Conference Training (13:00 – 17:00) Improving Post Approval Procedures of Research Ethics Committees B. FERCAP Steering Committee Meeting (17:30 – 20:00)
November 25 - 26, 2024 Monday – Tuesday	Conference Proper
November 27, 2024 Wednesday	FERCAP Recognition Program (9:00 to 12:00) Update FERCAP Surveyor Training on Recent Changes in International Guidelines (13:00 – 16:00)

Research is essential to generate innovative knowledge and evidence-based interventions to improve people's lives. The exponential increase in scientific knowledge has created a demand for effective systems that make use of innovative technology and novel approaches to enable wider use and popularization. Research as a social activity should result in better health and better quality of life of its target beneficiaries and the general population. Research with human participants should be conducted responsibly with proper attribution of duties and moral obligations among various stakeholders that include the sponsor, the investigator, the research ethics committee, the institution, regulators and public health authorities.

PRE - CONFERENCE AGENDA

Improving Post Approval Procedures of Research Ethics Committees

Sunday, November 24, 2022 (13:00 – 17:00)

Research Ethics Committees (RECs) are mandated to review and approve different types of protocols before they are implemented. Most RECs have developed standard assessment forms and procedures to ensure comprehensive review of the social value, scientific soundness and ethical compliance of research protocols. At the same time, RECs are tasked to monitor compliance with international and national guidelines during the implementation phase. While REC members have developed appropriate initial review competencies, proper monitoring of the implementation of approved protocols remains a challenge. The objective of this FERCAP training is to identify and share the best REC monitoring practices during the post approval phase.

Topics to be covered

REC Review of Post Approval Procedures

- Amendments
- Progress Report
- Final Report
- Protocol Deviation and Violation
- Serious Adverse Event/ Suspected Unexpected Serious Adverse Reaction/ Social Harm
- Site Visit
- Getting Feedback from Participants/ Investigators/ General Public

CONFERENCE AGENDA

DAY 1 – NOVEMBER 25, 2024

8:30 – 10:00 Nepal Time	Opening Ceremony	
Session Chairs	Dr. Gehanath Baral, Chairman , Nepal Health Research Council Dr. Kenji Hirayama, Chair , FERCAP	
	Welcome Remarks	Dr. Pramod Joshi, Member-Secretary (Executive Chief), NHRC

	Introduction of Country Delegates Introduction of Chief Guests/ Welcome Speeches	Dr. Kenji Hirayama, Chair , FERCAP
	KEYNOTE Speeches	
	Research for Equity and Justice	Prof. Dr. Sharad Raj Onta, Nepal Public Health Foundation
	WHO Guidance for Best Practices in Clinical Trials	Dr. Vasee Moorthy Senior Advisor, WHO R&D, Geneva, Switzerland
	Dr. Roshan Pokhrel	Secretary, Ministry of Health and Population
	Prof. Dr. Anjani Kumar Jha	Vice-Chairman, Nepal Medical Education Commission
	Prof. Dr. Shivaraj Adhikari	Vice-Chairman, National Planning Commission
	Mr. Pradip Paudel	Honorable Minister, Ministry of Health and Population
	Closing Remarks	Prof. Dr. Gehanath Baral, Nepal Health Research Council Chair
10:00-10:15	Session Break	
	Plenary Session	
10:15-12:30	Addressing Ethical Challenges in Health Research and Innovation	
Session 1	Session Chairs:	Juntra Laothavorn SIDCER-FERCAP President Ramesh Kant Adhikari , ERB Chair, NHRC
1.	Leadership of the Nepal Health Research Council in Health Ethics Governance	Pramod Joshi, Member-Secretary (Executive Chief), NHRC
2.	Ethical Challenges and Opportunities of Decentralized Clinical Trials	Jeremy Sugarman Johns Hopkins Berman Institute of Bioethics, USA
3.	Ethical Considerations in Climate Change and Neglected Tropical Disease Research	Vicente Belizario & Christian Cacatian University of the Philippines Manila
4	Developing a Framework to Prioritize Rare Inherited Disease in LMICs	Teguh Haryo Sasongko , IMU University, Malaysia Joseph Millum

		University of St. Andrews, UK
5	Establishing Regional Collaborative Partnerships among Academic Research Organizations	Muchanga Sifa Marie Joelle , National Center for Global Health and Medicine (NCGM) Japan & Kenji Hirayama FERCAP
6	Advancing Clinical Trials in Nepal: Overcoming Challenges and Implementing Solutions	Januka Khatri <i>et al.</i> Oxford University Clinical Research Unit, Nepal

12:30- 13:30	Lunch-break		
13:30-15:00	Parallel Sessions		
Session 2	Ethics Review of Social Science Research	Educating Research Stakeholders	Use of Technology in Ethics Review and Clinical Research
	Parallel Session 2A Hall-1	Parallel Session 2B Hall-2	Parallel Session 2C Hall-3
	Cristina Torres & Madhusudan Subedi	Im Hee Shin & Prakash Chandra Bhattarai	Fung Wei Chang & Bishesh Khanal
	<p>Panel Discussion: Proposed FERCAP Guidelines on the Ethics Review of Social Science Research Cristina E. Torres FERCAP Coordinator -----</p> <ul style="list-style-type: none"> Evaluation of Calcium and Vitamin D among Premenopausal vs. Menopausal Women Arun Dhungana <i>et al</i> Kathmandu Medical College, Nepal ----- Perspectives of Indigenous Tribal Healers Josna John B R & Vina Vaswani Yenepoya Center for Ethics, Mangalore, India 	<ul style="list-style-type: none"> A Context-Specific Casebook for Southeast Asian Bioethics Education Nishakanthi Gopalan & Joseph Ali, Universiti Malaya & Johns Hopkins University Conducting Educational Activities among Research Stakeholders Naraporn Prayoonwiwat, <i>et al</i> Siriraj Hospital Thailand Using Team Based Learning in Clinical Research Education Hui Chen Lee, Cathay General Hospital, Taiwan 	<p>Panel Discussion: Comparing Electronic IRB Experiences: NTUH eREC System</p> <p>Yi-Yu Chen et al National Taiwan University Hospital, Taiwan (R.O.C.) -----</p> <ul style="list-style-type: none"> Development of an Online Submission System Vinita Agrawal Sanjay Gandhi Post Graduate Institute India Effectiveness of Electronic Submission System Patompong Khaw-on Chiangmai University Thailand -----

	<ul style="list-style-type: none"> ● Historical Research Rhodalyn Wani-Obias University of the Philippines, Diliman, Philippines ● Protection of Privacy and Confidentiality Shama U Rao & Uma Kulkarni Yenepoya Center for Ethics, Mangalore, India ● Use of a Standard Ethics Assessment Form B-Jay Mosquera Department of Health Philippines 	<ul style="list-style-type: none"> ● Conducting Public Health Ethics Training among Local Policy Makers Myka Angela Cadag, Department of Health, Philippines ● Clinical Trial Training for the Research Teams Tsui Wen Hsu <i>et al</i> Cathay General Hospital, Taiwan 	<ul style="list-style-type: none"> ● Satisfaction with Electronic Submission Waraya Krisnoi Chulalongkorn University, Thailand ● Using AI for Rapid Classification Chien Liang Ho National Cheng Kung University, Taiwan ● Use of a Comprehensive Cloud Based Drug Tracking System Chien Liang Ho National Cheng Kung University, Taiwan
15:30- 15:45	Session Break		
15:45-17:15	Parallel Sessions		
Session 3	Strengthening Ethical Frameworks Breakout Rm. 1	Ethical Recruitment of Research Volunteers Breakout Rm. 2	Ethical Issues in Public Health Research Breakout Rm. 3
	Parallel Session 3A Hall-1	Parallel Session 3B Hall-2	Parallel Session 3C Hall-3
Chairs	Juntra Laothavorn & Janak Koirala	Aarati Shah & Ajit Rayamajhi	Vicente Belizario & Sujan Babu Marahatta
	<ul style="list-style-type: none"> ● Introduction: The Pandemic Ethics Project Rosemarie Bernabe ● Post-Trial Access in Latin America: Perceptions of Research Ethics Committee Members Fernando Hellmann The Experiences & 	<ul style="list-style-type: none"> ● Recruitment Strategies in Prison Research Mohd Jamili, Nur Hazwani Ministry of Health, Malaysia ● What Motivates Volunteering in Interventional Trials KV Ganpathy <i>et al</i> Tata Memorial Hospital 	<ul style="list-style-type: none"> ● Community Engagement in Promoting Rational Antimicrobial Use Nisha Jha <i>et al.</i> Laliput District, Nepal ● Identifying Hotspots in Visceral Leishmaniasis Endemic Areas Anand Ballabh Joshi Public Health and

	<p>Challenges of IDIs & FGDs for Pandemic Ethics Research Mohan Sharma & Namita Ghimire Tribhuvan University Nepal Health Research Council, Nepal -----</p> <p>Evolution of Post-Trial Access in LMICs- An Analysis of Indian Guidelines Nithya Gogtay King Edward Memorial Hospital (KEM), India -----</p> <ul style="list-style-type: none"> • Experiences of Research Participants about Post Trial Arrangements. Fatima Lorenzo Philippine Alliance of Patient Organizations (PAPO), Philippines ----- • Introduction: The AccessAfrica2 Project Rosemarie Bernabe ----- • Post-trial access: African Perspective- Kenya case study Beatrice Amugune ----- • Tanzania National Ethics Guideline review: the case of undisclosed PTA Ahmed Abdallah National Institute for Medical Research, Tanzania ----- 	<p>Mumbai, India</p> <ul style="list-style-type: none"> • Role of Community Recruiters in Vaccine Clinical Trials Orlie Lavilla <i>et al</i>, Philippine General Hospital • Feasibility of QuinteT Recruitment Intervention to Optimize Informed Consent Sangeetha Paramasivan <i>et al</i> University of Bristol, UK • Recruitment in Community Intervention Studies Patricia M. Khu <i>et al</i> Cardinal Santos Medical Center Philippines 	<p>Infectious Disease Research Center, Kathmandu, Nepal</p> <ul style="list-style-type: none"> • Prevalence of Vitamin B12 on Diabetic Patients on Metformin Shashi Sharma Rijal <i>et al</i>, Purbanchal University, Nepal • Community Engagement in Maternal and Infant Microbiome Study Arya Gautam, Sabitri Sciences, Nepal • Use of Discrete Choice Experiment in Pneumococcal Vaccine Jeffrey Pradeep Raj <i>et al</i>, Kasturba Medical College, India
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	<ul style="list-style-type: none"> • Joint Review Mechanism of Interventional Trials in Resource Limited Settings Christopher Ddamulira Uganda National Council for Science and Technology • Capacity Building Training for ERCs in Low Resource Settings Gudina Terefe Jimma University, Ethiopia • Strengthening Safety Reporting in Clinical Trials Marvin Buleera National Drug Authority, Uganda • Access Africa Guidelines on PTA for International Clinical Trials in Sub-Saharan Africa Vivian Mbanya University of Oslo, Norway 		
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18:00- 20:00 Cultural Program/ Dinner

Day 2: November 26, 2024			
08:30-10:30 Session 4	Parallel Sessions		
	Promoting Trust in Science	Vulnerability, Informed Consent and Assent Issues	Ethical Issues in Biomedical Research
	Parallel Session 4A Hall-1	Parallel Session 4B Hall-2	Parallel Session 4C Hall-3
Chairs	Kwanchanok Yimtae & Chop Lal Bhusal	Phanthipha Wongwai & Jeevan Bahadur Sherchand	Nurain Mohd Noor & Prakash Ghimire
	<ul style="list-style-type: none"> • The Role of Research Integrity: Insights from BEYOND and ROSiE projects Rosemarie Bernabe <i>et al</i>, University of Oslo 	<ul style="list-style-type: none"> • Reviewing Research Involving Vulnerable Participants Krishna Suvarnabhumi, Prince of Songkla 	<ul style="list-style-type: none"> • A Retrospective Study of the Profile of Leprosy Patients Suveksha Shaurya Shah, Lalgadh Leprosy Hospital, Nepal

	Norway	University, Thailand	
	<ul style="list-style-type: none"> • Exploring Open Science and One Health: The ROSiE Project's Perspective Naheeda Hamza University of Oslo Norway 	<ul style="list-style-type: none"> • Conducting Clinical Trials in Children Ram Hari Chapagain <i>et al</i>, Kanti Children's Hospital, Nepal 	<ul style="list-style-type: none"> • Investigation of Infectious Vaginitis and UTI Yamini Chhetri Tribhuvan University Nepal
	<ul style="list-style-type: none"> • Citizen Science and Clinical Trials: A New Frontier Judy Malundo University of Oslo, Norway 	<ul style="list-style-type: none"> • Adult Perception of Assent of Minors Ruth Ezeigbo & Ravi Vaswani, Yenepoya Center for Ethics, Mangalore, India 	<ul style="list-style-type: none"> • Off Label Medicine Use in India Likhith Prasanna <i>et al</i> Kasturba Medical College, India
	<ul style="list-style-type: none"> • Bridging Science Actors and Society: POIESIS and HYBRIDA projects Panagiotis Kavouras, Greece 	<ul style="list-style-type: none"> • Evaluation of Assent Forms for Children and Minors Charlotte Jane Joseph Ministry of Health, Malaysia 	<ul style="list-style-type: none"> • Prescribing Patterns and Adherence in Glaucoma Medication Anil Kumar Sah <i>et al</i> Eye Care Foundation Nepal
	<ul style="list-style-type: none"> • Stewards of Trust in Science: An overview from the VERITY Project Lisa Haberlein EUREC, Germany 	<ul style="list-style-type: none"> • Protection for Healthy Volunteers in Biomedical Research Francois Bompard INSERM Ethics Committee, France 	<ul style="list-style-type: none"> • Fasting vs. Carbohydrate Loading to Prepare for Femur Fracture Surgery Narendra Kumar Chaudary <i>et al</i> Nepal Orthopaedic Hospital
	<ul style="list-style-type: none"> • The Role of Research Ethics Committees (RECs): EUREC Network insights Dirk Lanzerath EUREC, Germany 	<ul style="list-style-type: none"> • Safeguarding Vulnerability during Digital Transformation Florabelle Taguiling University of the Philippines Diliman 	<ul style="list-style-type: none"> • Pain Management of Cancer Patients Mijala Bajracharya Manmohan Memorial Institute of Health Sciences, Nepal
10:30-11:00	Session Break		
11:00-12:30	Parallel Sessions		
Session 5	Navigating the Complexities of Implementation Research in Nepal	Evolution of Bioethics and Its Application to Human Research	Ethical Issues in Special Topics in Health Research

	Parallel Session 5A Hall-1	Parallel Session 5B Hall-2	Parallel Session 5C Hall-3
Chairs	Meghanath Dhimal & Rajendra Kumar BC (Moderator)	Vichai Chokvivat & Hari P Dhakal	Aphornpirom Ketupanya & Sudha Basnet
	<p>Panel Discussion: Ethical Complexities in Implementation Research in LMICs</p> <p>Panelists</p> <ul style="list-style-type: none"> Sabitri Sapkota Sambhav (Possible), Nepal Anand Ballabh Joshi Public Health and Infectious Disease Research Center, Kathmandu, Nepal Diptesh Aryal ERB Member, NHRC <p>Session Outcome: Actionable strategies for managing ethical issues in IR in LMICs</p>	<ul style="list-style-type: none"> Evolving Landscape of Research Ethics Gretchen Geneblaza Velarde <i>et al</i> University of the Philippines Diliman Meta-ethical Perspectives in Health Research Sachin Ghimire Tribhuvan University Nepal Ethical Oversight of Various Disciplines Ma. Frances Mallari University of the Philippines Diliman Artificial Intelligence Chatbots in Indian Health Care System Akshay Balakrishna <i>et al</i>, Kasturba Medical College, India Decoding Ethics of Authorship. Salik Ansari <i>et al.</i> Bhopal Hub, India 	<ul style="list-style-type: none"> A Systematic Literature Review of Pro-Environmental Behavior Richan Shrestha <i>et al</i> Kathmandu University Nepal Ethical Issues in Forensic Genetic Testing Ma. Corazon de Ungria University of the Philippines Diliman Genotype Characterization in Hepatitis C Virus in Patients Hari Prasad Kattel Tribhuvan University Nepal Ethics Review of Bioequivalence Studies Rita S. Sitorus Universitas Indonesia Neonatal Sepsis and Development Outcomes Swechhya Vaidya Amrita Institute of Medical Sciences and Researcher Center, India

			<ul style="list-style-type: none"> • Application of Research Ethics in Ayurveda Research Skanthesh Lakshmanan & Vina Vaswani Yenepoya Center for Ethics, Mangalore, India
12:30-13:30	Lunch Break and Poster Viewing		
13:30-15:00 Session 6	Monitoring Protocol Implementation Parallel Session 6A Hall-1	Perspectives of Ethics in the Health Sector Parallel Session 6B Hall-2	Improving REC Performance Parallel Session 6C Hall-2
Chairs	Naraporn Prayoonwiwat & Khem B Karki	Nandini Kumar & Sangeeta K Mishra	Magdarina Agtini & Pradip Gyanwali
	<ul style="list-style-type: none"> • Possible Under-reporting of Protocol Deviations and Violation Nurain Mohd Noor <i>et al</i>, Ministry of Health Malaysia 	<ul style="list-style-type: none"> • Ethical Leadership in Public Health Carl Abelardo T. Antonio University of the Philippines Manila 	<ul style="list-style-type: none"> • The Need for Bioethics Training for Community Volunteers and Researchers Ashok Kumar Mandal <i>et al</i>, Universiti Malaya, Malaysia
	<ul style="list-style-type: none"> • Development and Implementation of a Monitoring Tool Robyna Irshad Khan Aga Khan University Pakistan 	<ul style="list-style-type: none"> • Mapping research Trend in Sick Building Syndrome: A comprehensive review analysis Upama Ghimire <i>et al</i> 	<ul style="list-style-type: none"> • Enhancing the Role of Lay Members Numtip Smerchuar Phayao University Thailand
	<ul style="list-style-type: none"> • A Retrospective Review of Protocol Non-Compliance Edwin Ruamero, Jr. University of the Philippines Manila 	<ul style="list-style-type: none"> • Ethics Reporting in Publication Journals Jay A. Yacat <i>et al</i> University of the Philippines Diliman 	<ul style="list-style-type: none"> • Addressing Common issues of Researchers during Protocol Development Eti Nurwening Sholikhah <i>et al</i> Universitas Gadjah Mada, Indonesia
	<ul style="list-style-type: none"> • Value of REC Audit of Ongoing Studies Ami Fazlin <i>et al</i> Ministry of Health, 	<ul style="list-style-type: none"> • Perspectives in the Use of Electronic Health Information Siddhanth Rangineni <i>et al</i>, Kasturba Medical 	<ul style="list-style-type: none"> • Improving REC Communication with Research Stakeholders Kevin Martinez

	Malaysia	College, India	Department of Health Philippines
			<ul style="list-style-type: none"> • Ethical Issues in Reporting Research Results Mohan Raj Sharma, Institute of Medicine, Tribhuvan University, Nepal
15:30 -15:45	Session Break		
Session 7	Plenary Session		
15:45-17:30	Ensuring Responsible Conduct of Research		
	Session Chairs:	Vicente Belizario, Jr. FERCAP Steering Committee Mahesh Kumar Maskey	
	Promoting Responsible Conduct of Research through Global Networks	Mahnaz Vahedi WHO-TDR, Geneva, Switzerland	
	Upholding Research Integrity through Responsible Conduct of Research	Tang Swee Ping, Ministry of Health, Malaysia	
	Ethical Consideration in a Community Vaccine Trial	Ashata Dahal, Oxford University Clinical Research Unit, Nepal	
	The Role of the Institution in the WHO Global Benchmarking Tool	Cristina E. Torres University of the Philippines Manila	
	Establishment of Regional Pipelines for Medicinal Products Against Pandemics	Kwanchanok Yimtae Mahidol University Kenji Hirayama Nagasaki University	
17:15-17:30	Closing Ceremony	Prof. Dr.Kenji Hirayama	
	Invitation to the 2025 FERCAP Conference	Faculties of Medicine, Mahidol University, Thailand	
	Vote of Thanks	Dr.Pramod Joshi Member Secretary (Executive Chief), NHRC	

**FERCAP General Assembly: November 27, 2024
(9:00-12:00)**

Welcome Remarks	Prof. Dr.Kenji Hirayama FERCAP Chair
Awarding of Certificates of Appreciation	FERCAP Partners in Nepal
FERCAP Reports	Prof. Dr.Cristina Torres FERCAP Coordinator Prof.Kesara Na Banchang FERCAP Treasurer
Recognition Ceremony	Prof.Dr. Juntra Laothavorn SIDCER President
Accomplishment Awards	
Vote of Thanks	Prof. Dr.Gehanath Baral NHRC Chair
Closing Remarks	Prof. Dr.Kenji Hirayama FERCAP Chair

**Update FERCAP Surveyor Training on Recent Changes in International Guidelines (13:00
-16:00)**

<ul style="list-style-type: none"> • WHO Global Benchmarking Tool for RECs (2023) • Declaration of Helsinki (2024) • Directions of ICH-GCP (E6) (R3) 	FERCAP Training Team
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