

# 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	A. Pre-Conference Training (13:00 – 17:00)	
Sunday	<ul><li>Improving Post Approval Procedures of Research Ethics Committees</li><li>B. FERCAP Steering Committee Meeting (17:30 – 20:00)</li></ul>	
November 25 - 26, 2024 Monday – Tuesday	Conference Proper	
November 27, 2024 Wednesday	FERCAP Recognition Program	

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

## <u>Sunday, November 24, 2022 (13:00 – 17:00)</u>

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**

9:00 – 10:00 Nepal Time	Opening Ceremony	
	Session Chair	Kenji Hirayama
	Introduction of Country Delegates	<b>Kenji Hirayama</b> FERCAP Chair
	Welcome Remarks	Nepal Health Research Council Dr. Pramod
	KEYNOTE Address	
	Promoting Responsible Conduct of Scientific Research	Sharad Raj Onta
	Promoting Responsible Conduct of Research through Global Networks	Mihai Mihut WHO-TDR, Geneva, Switzerland

10:00-10:15	Session Break		
	Plenary Session		
10:15-12:30	Addressing Ethical Challenges in Hea	lth Research and Innovation	
Session 1	Session Chairs:	Juntra Laothavorn	
		SIDCER-FERCAP	
		I. C.	
	Ethical Challenges and	Jeremy Sugarman	
	Opportunities of Decentralized	Johns Hopkins Berman Institute of	
	Clinical Trials	Bioethics, USA	
	Ethical Considerations in Climate	Vicente Belizario & Christian Cacatian	
	Change and Neglected Tropical	University of the Philippines Manila	
	Disease Research		
	Developing a Framework to	Teguh Haryo Sasongko, IMU	
	Prioritize Rare Inherited Disease in	University, Malaysia & Joseph Millum	
	LMICs	University of St. Andrews, UK	
	Advancing Clinical Trials in Nepal:	Januka Khatri <i>et al.</i>	
	<b>Overcoming Challenges and</b>	Oxford University Clinical Research	
	Implementing Solutions	Unit, Nepal	
	Leadership of the Nepal Health	Gehanath Baral,	
	<b>Research Council in Health Ethics</b>	Kathmandu University	
	Governance		
	Establishing Regional Collaborative	Kouji Wada & Kenji Hirayama.	
	Partnerships among Academic	Japan Agency for Medical Research	
	<b>Research Organizations</b>	and Development	

12:30-13:30	Lunchbreak		
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
	Breakout Rm. 1	Breakout Rm. 2	Breakout Rm. 3
	Parallel Session 2A	Parallel Session 2B	Parallel Session 2C
	Panel Discussion:	A Context Specific	Panel Discussion:
	FERCAP Guidelines on	Casebook for	<b>Comparing Electronic</b>
	the Ethics Review of	Southeast Asian	IRB Experiences
	Social Science Research	<b>Bioethics Education</b>	NTUH eREC System
	Cristina E. Torres	Nishakanthi Gopalan &	Yi Yu Chen
	FERCAP Coordinator	Joseph Ali, Universiti	National Taiwan
	Use of a Standard	Malaya & Johns	University
	Ethics Assessment	Hopkins University	Development of an
	Form	Conducting	Online Submission
		Educational Activities	System
		among Research	Vinita Agrawal
		Stakeholders	

	B-Jay Mosquera	Peeraya	Sanjay Gandhi Post
	Department of Health Philippines Case Studies • Business Ethics Siti Hazlina, USM Malaysia	Chaowalitwong <i>et al</i> Siriraj Hospital Thailand	Graduate Institute India
	Evaluation of Calcium and Vitamin D among Premenopausal vs. Menopausal Women Arun Dhungana <i>et al</i> Kathmandu Medical College, Nepal	<ul> <li>Using Team Based Learning in Clinical Research Education Hui Chen Lee, Cathay General Hospital, Taiwan</li> </ul>	Effectiveness of Electronic Submission System Patompong Khaw-on Chiangmai University Thailand
	Historical Research     Rhodalyn Wani-Obias     University of the     Philippines, Diliman	<ul> <li>Conducting Public Health Ethics Training among Local Policy Makers</li> <li>Myra Cagdag,</li> <li>Department of Health,</li> <li>Philippines</li> </ul>	<ul> <li>Satisfaction with Electronic Submission</li> <li>Waraya Krisnoi</li> <li>Chulalongkorn</li> <li>University, Thailand</li> </ul>
	<ul> <li>Autism Study Machhindra Lamichhane, Tribhuvan University Nepal</li> </ul>	Clinical Trial Training for the Research Teams Tsui Wen Hsu <i>et al</i> Cathay General Hospital, Taiwan	<ul> <li>Using AI for Rapid Classification</li> <li>Use of a Comprehensive Cloud Based Drug Tracking System Chien Liang Ho National Cheng Kung University, Taiwan</li> </ul>
15:30- 15:45		Session Break	
15:45-17:00		Parallel Sessions	
Session 3	Strengthening Ethical and Frameworks Breakout Rm. 1	Ethical Recruitment of Research Volunteers Breakout Rm. 2	Ethical Issues in Public Health Research Breakout Rm. 3
	Parallel Session 3A	Parallel Session 3B	Parallel Session 3C
	<ul> <li>Capacity Building in Clinical Trial Frameworks in Asia and Africa</li> </ul>	<ul> <li>Recruitment Strategies in Prison Research Mohd Jamil Universiti Malaya</li> </ul>	Community     Engagement in     Promoting Rational     Antimicrobial Use
		Onversiti Malaya	Antimicrobial Use

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	Rosemarie Bernabe	Malaysia	Nisha Jha <i>et al.</i>
	University of Oslo,		Laliput District, Nepal
	Norway		
•		<ul> <li>What Motivates         Volunteering in         Interventional Trials         KV Ganpathy et al         Tata Memorial         Hospital         Mumbai, India         </li> </ul>	Identifying Hotspots in Visceral Leishmaniasis Endemic Areas Anand Ballabh Joshi Public Health and Infectious Disease Research Center, Kathmandu, Nepal
•	• Updates on Ethics Capacity-Building in Uganda and Ethiopia AccessAfrica2 Partners	<ul> <li>Role of Community Recruiters in Vaccine Clinical Trials Ralph Elvi Villalobos, Philippine General Hospital</li> </ul>	A Thematic Analysis of TB-DOTS Healthcare Delivery Alexandra Bayola <i>et al</i> University of Sto. Tomas, Philippines
		Feasibility of QuinteT     Recruitment     Intervention to     Optimize Informed     Consent     Nithya Gogtay et al     Seth GS Medical     College	<ul> <li>Prevalence of Vitamin B12 on Diabetic Patients on Metformin Shashi Sharma Rijal et al, Purbanchal University, Nepal</li> </ul>
		Recruitment in Community Intervention Studies Patricia M. Khu <i>et al</i> Cardinal Santos Medical Center	Community     Engagement in     Maternal and Infant     Microbiome Study     Arya Gautam, Sabitri     Sciences, Nepal
		Philippines	
17:30- 19:30 C	Cultural Presentation and		

	Day 2: November 26, 2024		
09:00-10:30	Parallel Sessions		
Session 4	Promoting Trust in Science	Vulnerability, Informed Consent and Assent Issues	Ethical Issues in Biomedical Research
	Breakout Rm. 1	Breakout Rm. 2	Breakout Rm. 3
	Parallel Session 4A	Parallel Session 4B	Parallel Session 4C
	<ul> <li>Open Science as a Vehicle for Benefit sharing</li> <li>Research Integrity to Promote Trust in Science Rosemarie Bernabe et al, University of Oslo Norway</li> </ul>	<ul> <li>Reviewing Research Involving Vulnerable Participants Krishna Suvarnabhumi, Prince of Songkla University, Thailand</li> </ul>	<ul> <li>A Retrospective Study of the Profile of Leprosy Patients Suveksha Shaurya Shah, Lalgadh Leprosy Hospital, Nepal</li> </ul>
	<ul> <li>Promoting Trust between Science Actors and Society Panagiotis Kavouras, Greece</li> </ul>	Conducting Clinical Trials in Children Ram Hari Chapagain <i>et</i> <i>al,</i> Kanthi Children's Hospital, Nepal	<ul> <li>Investigation of Infectious Vaginitis and UTI Yamini Chhetri Tribhuvan University Nepal</li> </ul>
	Stewards of Trust as Key Players in the Research Ecosystem Lisa Haberlein EUREC, Germany	Evaluation of Assent Forms for Children and Minors Charlotte Jane Joseph Ministry of Health, Malaysia	Pain Management of Cancer Patients Mijala Bajracharya Manmohan Memorial Institute of Health Sciences, Nepal
	Perspectives from the European Networks of RECs Dirk Lanzerath EUREC, Germany	Optimizing Informed Consent in Clinical Trials Nithya J Gogtay <i>et al</i> Seth GS Medical Center, India	<ul> <li>Prescribing Patterns and Adherence in Glaucoma Medication Avil Gautam <i>et al</i> Eye Care Foundation Nepal</li> </ul>
		<ul> <li>Safeguarding Vulnerability during Digital Transformation</li> <li>Florabelle Taguiling</li> <li>University of the</li> <li>Philippines Diliman</li> </ul>	<ul> <li>Fasting vs. Carbohydrate Loading to Prepare for Femur Fracture Surgery Narendra Kumar Chaudary <i>et al</i> Nepal Orthopaedic Hospital</li> </ul>

10:30-11:00	Session Break		
11:00-12:30	Parallel Sessions		
Session 5	Navigating the Complexities of Implementation Research in Nepal Breakout Rm. 1	Evolution of Bioethics and Its Application to Human Research Breakout Rm. 2	Ethical Issues in Special Topics in Health Research Breakout Rm. 3
	Parallel Session 5A	Parallel Session 5B	Parallel Session 5C
	Panel Discussion: Ethical Complexities in Implementation Research	<ul> <li>Evolving Landscape of Research Ethics</li> <li>Gretchen Geneblaza</li> <li>Velarde <i>et al</i></li> <li>University of the</li> <li>Philippines Diliman</li> </ul>	<ul> <li>A Systematic Literature Review of Pro-Environmental Behavior Richan Shresta <i>et al</i> Kathmandu University Nepal</li> </ul>
	<ul> <li>Panelists</li> <li>Archana Shrestha, Kathmandu University School of Medical Sciences</li> <li>Megha Raj Banjara, Central Department of Microbiology, Tribhuvan University</li> </ul>	<ul> <li>Meta-ethical Perspectives in Health Research Sachin Ghimere Tribhuvan University Nepal</li> </ul>	Ethical Issues in Forensic Genetic Testing Ma. Corazon de Ungria University of the Philippines Diliman
	<ul> <li>Sabitri Sapkota, Executive Director</li> <li>Diptesh Aryal Nepal Intensive Care Research Foundation</li> </ul>	Ethical Oversight of Various Disciplines Ma. Frances Mallari University of the Philippines Diliman	<ul> <li>Genotype Characterization in Hepatitis C Virus in Patients Hari Prasad Kattel Tribhuvan University Nepal</li> </ul>
	Session outcome: Actionable strategies for managing ethical issues in IR in LMICs.	<ul> <li>Digitization of Data as a Path to Responsible Conduct of Research Jyoti U. Devcota Kathmandu University Nepal</li> </ul>	Ethics Review of Bioequivalence Studies Rita S. Sitorus Universitas Indonesia
		<ul> <li>Decoding Ethics of Authorship.</li> <li>Salik Ansan <i>et al.</i></li> <li>Bhopal Hub, India</li> </ul>	<ul> <li>Neonatal Sepsis and Development</li> <li>Outcomes</li> <li>Swechhya Vaidya</li> <li>Paropkar Maternity</li> <li>and Women's Hospital</li> </ul>

			Nepal
12:30-13:30	Lunch Break and Poster	Viewing	
13:30-15:00 Session 6	Monitoring Protocol Implementation Breakout Rm. 1 Parallel Session 6A	Perspectives of Ethics in the Health Sector Breakout Rm. 2 Parallel Session 6B	Improving REC Performance Breakout Rm. 3 Parallel Session 6C
	<ul> <li>Possible Under- reporting of Protocol Deviations and Violation Nurain Mohd Noor <i>et</i> <i>al</i>, Ministry of Health Malaysia</li> </ul>	Ethical Leadership in Public Health Carl Abelardo T. Antonio, University of the Philippines Manila	The Need for Bioethics     Training for     Community     Volunteers and     Researchers     Ashok Kumar Mandal     et al, Universiti     Malaya, Malaysia
	<ul> <li>Development and Implementation of a Monitoring Tool Robyna Irshad Khan. Aga Khan University Pakistan</li> </ul>	<ul> <li>A Bibliometric Analysis of Sick Building Syndrome Upama Ghimere <i>et al</i> Southeast University Nanjing, China</li> </ul>	Enhancing the Role of Lay Members Numtip Smerchuar Phayao University Thailand
	<ul> <li>Protocol Deviations in Regulatory Clinical Trials Chaudhari VL <i>et al.</i> Seth GS Medical College, India</li> </ul>	Ethics Reporting in Publication Journals Jay A. Yacat <i>et al</i> University of the Philippines Diliman	<ul> <li>Addressing Common issues of Researchers during Protocol</li> <li>Development</li> <li>Eti Nurwening</li> <li>Sholikhah et al</li> <li>Universitas Gadjah</li> <li>Mada, Indonesia</li> </ul>
	A Retrospective     Review of Protocol     Non-Compliance     Edwin Ruamero, Jr.     University of the     Philippines Manila	<ul> <li>Rethinking the Term 'Lay Person' Shamima Parvin Lasker <i>et al.</i> Bangladesh Bioethics Society</li> </ul>	Improving REC Communication with Research Stakeholders Kevin Martinez Department of Health Philippines
	<ul> <li>Value of REC Audit of Ongoing Studies Ami Fazlin <i>et al</i> Ministry of Health, Malaysia</li> </ul>	An Ethical Perspective     of Research Fatigue     Felishana Cherop     MOI University, Kenya	<ul> <li>Ethical Issues in Reporting Research Results. Mohan Raj Sharma.</li> </ul>

				Tribhuvan University Hospital, Nepal
Session 7	Ι	Plenary	Session	
15:30-17:00	Ensuring Responsible Conduct	of Res	earch	
	Session Chairs:		FERCAP Ste	eering Committee
	Upholding Research Integrity through Responsible Conduct of Research	of	Asyraf Syahi of Health, Ind	mi Mohd Noor, Ministry donesia
	Ethical Consideration in a Community Vaccine Trial			l, Oxford University earch Unit, Nepal
	Addressing Ethical Issues in Machine Learning Applications			DCER, Thailand
	Integrating the WHO Global Benchmarking Tool Elements Responsible Conduct of Resear		Cristina E. T FERCAP	orres
	Establishment of Regional Pipe for Medicinal Products Against Pandemics	elines	Kenji Hiraya FERCAP Kwanchanok	
			Mahidol Uni	versity
17:00-17:30	Closing Ceremony Invitation to the 2025 FERCAR Conference	•	Kenji Hiray Faculties of University, 7	Medicine, Mahidol

FERCAP General Assembly: November 27, 2024 (9:00-12:00)		
Welcome Remarks	Kenji Hirayama	
	FERCAP Chair	
Awarding of Certificates of Appreciation	FERCAP Partners in Nepal	
FERCAP Reports	Cristina Torres	
	FERCAP Coordinator	
	Kesara Na Banchang	
	FERCAP Treasurer	
Recognition Ceremony	Juntra Laothavorn	
	SIDCER Coordinator	
Accomplishment Awards	Juntra Laothavorn	
	SIDCER Coordinator	
Closing Remarks	Kenji Hirayama	
	FERCAP Chair	