

Responsible Conduct of Research in Asia and the Western Pacific: Insights from the 24th Forum for Ethical Review Committees in the Asian and Western Pacific Region International Conference

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ABSTRACT

Background: Research Ethics Committees (RECs) play a critical role in safeguarding ethical integrity in health research by reviewing protocols for scientific validity, social value, and ethical compliance. FERCAP, a regional initiative under WHO-TDR, has supported harmonization and capacity building in research ethics across the Asia-Pacific region for the past 25 years. The 24th FERCAP International Conference, hosted by the Nepal Health Research Council in 2024, provided a platform to examine ethical challenges and innovations under the theme “Maximizing Benefits through Responsible Conduct of Research.”

Methods: A cross-sectional qualitative study was conducted using secondary data sources from the conference, including video recordings, agendas, presentations, transcripts, and reports. Descriptive analysis was performed on participant demographics, while thematic analysis was applied to content from plenary and parallel sessions. Three researchers independently coded the data and identified major themes through consensus.

Results: The conference was attended by over 500 participants from 23 countries and featured presentations across 18 thematic sessions. Three primary themes emerged: strengthening ethical oversight through post-approval monitoring and capacity building; promoting inclusivity and contextual relevance in ethics review, especially in social science and community-based research; and addressing emerging ethical issues posed by new technologies and decentralized trials. Discussions also emphasized integrating open science principles, harmonizing international guidelines, and recognizing institutional contributions to ethics governance.

Conclusion: The findings from the 24th FERCAP Conference highlight the region’s progress and challenges in upholding ethical standards amidst rapidly evolving research contexts. The conference reinforced the need for collaborative frameworks, continued ethics training, and responsive policies that address both biomedical and social research landscapes. These outcomes will inform future directions as FERCAP prepares for its 25th anniversary and continues to strengthen ethical research environments across the region.

Keywords: Ethical review; FERCAP; NHRC; post-approval; research ethics committees.

INTRODUCTION

Research Ethics Committees (RECs) are mandated to review research protocols to ensure their social value, scientific rigor, and ethical compliance prior to implementation, using standardized assessment forms and procedures¹. These ethical review systems are fundamental to safeguarding the integrity and societal relevance of health research. Beyond initial review, RECs also monitor adherence to national and international ethical guidelines throughout the research process.¹

The Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP) was established in 2000 as a regional initiative to strengthen ethical review systems and promote responsible research conduct. Affiliated with the Faculty of Allied Health Sciences (FAHS) at Thammasat University, FERCAP operates as a project under the World Health Organization’s (WHO) Special Programme for Research and Training in Tropical Diseases (TDR). It functions as a regional forum within the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER).²

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Last 25 years, FERCAP has been instrumental in advancing ethical standards across diverse cultural and regulatory contexts, fostering harmonization of research ethics among countries with varying legal and institutional frameworks. The 24th FERCAP International Conference, held in Kathmandu, Nepal from November 24-27, 2024, was hosted by the Nepal Health Research Council (NHRC) and centered on the theme, "Maximizing Benefits through Responsible Conduct of Research".³ This article thus aims to explore the discussions and recommendations of the conference.

METHODS

This is a proceeding article which involved the review and analysis of secondary information retrieved from the electronic documents (agenda, presentation, video recording, transcripts, program related documents) from the 24th FERCAP International Conference held in Nepal.

Descriptive analysis was performed on the available quantitative data, including the characteristics of the participants. Thematic analysis was conducted on the content gathered from the conference. Authors independently reviewed and coded the data, subsequently reaching consensus on three overarching themes.

Informal discussion during the program, information not related to the objective of the program and any information that reveals the identity of the participants were excluded from the analysis.

RESULTS

The conference was co-organized by the NHRC and FERCAP, convening over 500 participants, including representatives from Institutional Review Committees (IRCs), policymakers, researchers, and international experts from 23 countries. The program featured a comprehensive schedule, beginning with a pre-conference day focused on training to improve post-approval procedures for Research Ethics Committees (RECs) and the FERCAP Steering Committee meeting on Day 0, followed by the main two-day conference, and concluding with the FERCAP General Assembly meeting on Day 3. The full agenda is provided in the supplementary material (S1). Day 1 of the conference had the inauguration, one plenary session and six parallel technical sessions while Day 2 offered one plenary session and nine parallel technical sessions.

The conference encompassed plenary sessions, keynote lectures, panel discussions, country and institutional reports, and breakout working groups, fostering in-depth dialogue on policy development, ethics education, accreditation processes, and regional networking opportunities. NHRC took a central role in managing logistics and facilitating discussions, while also highlighting Nepal's advancements in institutionalizing research ethics through the implementation of digital platforms and tailored standard operating procedures (SOPs).

Pre-conference workshop

The pre-conference workshop organized on Day 0, 24 November 2024, focused on strengthening post-approval procedures of Research Ethics Committees, emphasizing ethical oversight through scientific rigor, informed consent, and participant protection.

The workshop emphasized the crucial role of ethical oversight in clinical research, particularly during protocol amendments and post-approval phases. IRCs were highlighted as central to ensuring participant safety and research integrity, with different procedures applied to minor and major amendments. A COVID-19 vaccine trial revealed significant ethical breaches, such as participant ineligibility, poor informed consent, and unauthorized drug use. These lapses reinforced the need for strict adherence to international standards like Council for International Organizations of Medical Sciences (CIOMS) and International Council for Harmonisation Good Clinical Practice (ICH-GCP) guidelines. The importance of timely Severe Adverse Events (SAE) reporting and transparency in safety monitoring was underscored throughout. IRB site visits emerged as vital tools for improving protocol compliance, especially in high-risk or vulnerable populations. Overall, presentations stressed the need for rigorous ethical standards across all clinical research stages.

Recommendations included updating Patient Information Sheets (PIS) to reflect any risk changes and creating clear guidelines to categorize amendments by impact. Establishing systems for long-term assessment of amendments was also proposed to ensure ongoing participant protection. GCP training should be mandatory for all clinical research personnel to improve protocol adherence and close ethical gaps. Strengthened monitoring systems, including routine site visits and CAPA reviews, were encouraged to ensure accountability. SOPs should mandate SAE reporting within 24 hours, including for non-serious

events, to enhance safety tracking. Site visits should include educational feedback, protocol reviews, and documentation audits to foster compliance. Ethics committees must be empowered with resources and authority to actively guide and enforce ethical conduct throughout trials.

The Q&A session focused on addressing real-world ethical dilemmas in trial oversight. Presenters clarified that when protocol violations occur, Ethics Committees must not only recommend but also verify implementation of corrective actions. Inquiries about journal-requested title changes were addressed by distinguishing the Ethics Committee's responsibility for protocol titles from editorial adjustments made by journals. On non-compliance by Principal Investigators, it was explained that unapproved changes are protocol deviations requiring both violation and amendment reports. A Nepali participant raised concerns about recruitment and compensation in low-funded trials, prompting experts to call for country-specific compensation strategies and stronger institutional monitoring. Examples from India and the Philippines showed difficulties in academic research insurance, highlighting the need for institutional support funds. WHO's benchmarking tools were cited as helpful in defining institutional responsibilities, revealing a gap in current GCP guidelines.

The pre-conference workshop concluded with a unified call for stronger moral and legal accountability from both investigators and institutions to uphold participant safety.

Conference proper

Day 1

The official conference commenced with a grand opening ceremony on 25 November 2024, held at the Everest Hotel in Kathmandu. The event was inaugurated by the Hon'ble Minister of Health and Population of Nepal, who served as the chief guest for the occasion.

National and international dignitaries graced the ceremony, delivering insightful and inspiring remarks that underscored the importance of fostering responsible research practices. Their contributions helped set a collaborative and forward-looking tone for the days ahead.

This powerful launch laid the foundation for meaningful dialogue and active engagement throughout the

conference on Maximizing Benefits Through Responsible Conduct of Research.

Plenary session 1: Addressing Ethical Challenges in Health Research and Innovation - The session emphasized Nepal's leadership in promoting ethical health research through grants, digital platforms, policy integration, and decentralization of review systems. Presentations highlighted the need for decentralized clinical trials (DCTs) to uphold core ethical principles while ensuring inclusivity and robust oversight. Ethical responses to challenges such as climate change and neglected tropical diseases were underscored, with a call for multidisciplinary, equity-focused research strategies. Strengthening research capacity through funding, infrastructure, and academic leadership was identified as essential for sustaining ethical innovation. During the Q&A, participants explored the potential of DCTs to reduce trial costs and enhance resilience, while stressing the need for IRB training and collaborative learning to support ethical adaptation in evolving research landscapes.

Parallel Session 2A: Ethics Review of Social Science Research - The session emphasized the need for clear objectives, rigorous methods, and ethical integrity in social science research, particularly in promoting social impact. Presenters discussed how cultural sensitivities and concerns over plagiarism may limit knowledge sharing but also serve to protect community identity. Future directions included culturally validated tools, stronger privacy safeguards, and researcher training focused on accountability and participant rights.

Parallel Session 2B: Educating Research Stakeholders - Innovative teaching tools like Team-Based Learning (TBL) and regional case studies in bioethics were recognized as effective for building ethical understanding. Presenters advocated for the creation of practical resources, such as FAQs and repositories, to support investigators. Ongoing training, feedback systems, and engagement with public health ethics committees were deemed essential to keep ethical oversight relevant and responsive.

Parallel Session 2C: Use of Technology in Ethics Review and Clinical Research - The integration of AI tools and automated systems into IRB workflows was shown to enhance efficiency, accuracy, and user satisfaction. Technologies like AI IRCD AI, CU-REC (Central University-Research Ethics Committee), and IWIS (Interactive Web-Based Inventory System) were praised for improving protocol classification and communication. Future goals

included expanding platform interoperability, applying machine learning for predictive oversight, and exploring blockchain for secure data management.

Parallel Session 3A: Strengthening Ethical Frameworks - Ethical access to post-trial interventions was highlighted as a critical gap, especially in low-resource settings, calling for enforceable and inclusive PTA (Post Trial Access) policies. The session identified methodological challenges in pandemic-era research, particularly around qualitative data collection and participant follow-up. Capacity building for ERCs and standard setting in post-trial ethics were proposed as immediate regional priorities.

Parallel Session 3B: Ethical Recruitment of Research Volunteers - The session focused on protecting rights in sensitive contexts like prisons, emphasizing the importance of transparent, voluntary recruitment practices. Presenters noted that healthcare professionals often hold misconceptions about clinical trials, which structured education programs could help address. Future recommendations included ensuring justice in access to research participation and enhancing community-based recruitment strategies.

Parallel Session 3C: Ethical Issues in Public Health Research - Community-based ethical research, such as antimicrobial use interventions among mothers, was presented as a promising model for behavior change. Speakers emphasized the urgent need for better surveillance and public health infrastructure to address the spread of diseases like Visceral Leishmaniasis. The session also stressed incorporating local scientific leadership and understanding vaccine hesitancy through social and demographic lenses to guide ethical and effective public health research.

Day 2

Parallel Session 4A: Promoting Trust in Science - This session emphasized the importance of open science in increasing transparency, minimizing misconduct, and improving global access to multilingual knowledge. Presenters stressed the need for collective accountability across researchers, institutions, and policymakers to uphold research integrity. Citizen science was recognized for strengthening trust and data quality, while RECs were urged to support rather than hinder ethical responsibility.

Parallel Session 4B: Vulnerability, Informed Consent and Assent Issues - The session explored ethical complexities

in research involving vulnerable populations, particularly during crises like the COVID-19 pandemic. Presenters highlighted challenges in implementing vaccine trials due to delays and infrastructure limitations and emphasized the importance of nuanced vulnerability classification and child assent. Future steps included revising consent tools, strengthening volunteer protections, and developing context-sensitive ethical frameworks. Ethics Research Committees, which are crucial for safeguarding human research participants, must be informed of the particular risks healthy volunteers face, especially since specific protective laws and regulations for these volunteers are scarce globally.

Parallel Session 4C: Ethical Issues in Biomedical Research - Discussions in this session addressed ethical concerns in gender-sensitive and neglected health conditions, such as leprosy and urinary tract infections. Concerns over unregulated off-label drug use and poor adherence to treatment regimens were central, alongside calls for more personalized patient care. Recommendations included improving public education, regulatory oversight, and research methodologies in biomedical ethics.

Parallel Session 5A: Navigating the Complexities of Implementation in Nepal - This session discussed the need for cautious piloting of new interventions and the ethical evaluation of risks in implementation research, especially in LMICs. Community engagement and consent transparency were emphasized as foundations of ethical practice. The session called for improved data protection, ERB capacity, and stronger researcher-policy collaboration for equitable, impactful research.

Parallel Session 5B: Evolution of Bioethics and Its Application to Human Research - This session highlighted bioethics as an evolving, context-sensitive discipline requiring flexibility without compromising core values. Concerns were raised about authorship ethics, expedited reviews in emergencies, and ethical tensions between outcome-driven and duty-based frameworks. The ethical integration of AI into mental health research was flagged as a critical area for future discourse.

Parallel Session 5C: Ethical Issues in Special Topics in Health Research - Ethical concerns were explored in areas like environmental behavior, hepatitis C treatment, and Ayurveda. Presenters advocated for culturally grounded research frameworks and more adaptive methodologies for traditional medicine. The session stressed on surprise audits, long-term studies, and better pediatric follow-up to uphold ethics across

diverse health topics.

Parallel Session 6A: Monitoring Protocol Implementation - This session focused on expanding ethics oversight through monitoring of investigator-led studies and system-level improvements like the NMRR (National Medical Research Register). Presenters stressed training and routine protocol reviews as key to enhancing institutional ethical cultures. Future directions included real-time monitoring systems, integrated feedback loops, and broader compliance reviews.

Parallel Session 6B: Perspectives of Ethics in the Health Sector - Presenters challenged exclusionary ethics terminology and emphasized respectful language to promote engagement. Ethical concerns over research fatigue in over studied communities and inadequate data privacy policies were discussed. Harmonized privacy frameworks and a more responsive, inclusive ethics culture was proposed as essential to modern research ethics.

Parallel Session 6C: Improving REC Performance - This session focused on enhancing REC effectiveness through tailored training, community bioethics, and better lay member involvement. Scientific misconduct was identified as a major challenge, demanding stronger accountability systems. Future strategies included standardized training modules and global knowledge-sharing to harmonize ethical review standards.

Plenary session 7: Ensuring Responsible Conduct of Research - The session underscored a significant capacity gap among ERCs, particularly in effectively engaging communities and empowering layperson participation, as the meaningful inclusion remains a challenge, weakening the balance and inclusivity of ethical reviews. Regional successes in institutionalizing responsible research practices were presented as models, with a strong call for mandatory, structured ethics training for both ERC members and researchers. Multi-sectoral collaboration across government, academia, and the private sector was highlighted as vital for building sustainable, ethically sound research ecosystems. Future priorities included creating robust governance frameworks, ensuring informed consent, and establishing mechanisms for community feedback to foster trust and accountability in health research.

The closing ceremony marked a thoughtful end to the three-day conference on *“Maximizing Benefits Through Responsible Conduct of Research”*, with a heartfelt acknowledgment of Nepal's pivotal contributions to

promoting ethical research practices.

Key highlights included:

Recognition of Nepal's leadership and initiatives in fostering responsible research conduct.

Expressions of gratitude to all in-person and online participants, distinguished speakers, and collaborators.

Appreciation of the collective efforts that made the conference a meaningful and impactful success.

The Nepal Health Research Council extends its sincere thanks to everyone whose dedication and insights helped shape this event into a vibrant platform for dialogue, learning, and collaboration.

General Assembly

On Day 3, 27 November 2024, the FERCAP General Assembly began with opening remarks by national and international speakers. Ethics committees from multiple countries were recognized, with special honors given to Thailand's National Science and Technology Development Agency - Institutional Review Board (NSTDA-IRB) for their exceptional contributions.

FERCAP's achievements in 2024 reflected both regional leadership and global relevance, with over 500 participants from 23 countries attending the conference. Strong partnerships were emphasized with national accreditation systems from different countries and the NHRC Nepal. The network's training collaborations with leading universities helped advance capacity-building efforts, while updates on international standards such as WHO Benchmarking Tools, the 2024 Declaration of Helsinki, and ICH-GCP Rev 3 ensured alignment with evolving ethics landscapes. FERCAP's financial stability, with a reported balance of \$15,697, was also noted as a foundation for sustained operations. The event underscored the vital role of ethics committees in improving the quality of clinical and social science research and highlighted their contributions to safeguarding research integrity. Thirty committees from across Asia were recognized for their ongoing efforts and institutional development. The shared commitment to ethical research practices created a unifying theme for this year's assembly.

Future directions included expanding recognition of IRBs in underserved regions and developing advanced training modules on AI and global health challenges.

Increased focus on ethics in social science research, local guideline development, and collaboration with EU-funded initiatives were highlighted. FERCAP stressed to diversify its funding, highlight the societal impact of ethics, and celebrate 25 years of progress at the 2025 conference in Thailand.

DISCUSSION

The 24th FERCAP International Conference served as a crucial platform to evaluate the evolving landscape of research ethics in Asia and the Western Pacific, with an emphasis on promoting the responsible conduct of research. The diverse representation of over 150 participants from more than ten countries reflects FERCAP's sustained success in fostering regional collaboration and harmonizing ethical standards. Compared to previous years, the inclusion of digital platforms, AI-based ethics tools, and decentralized clinical trials (DCTs) signals a notable shift towards innovation while maintaining ethical rigor. These developments echo global trends where ethics committees are adapting to new technologies and data governance frameworks to ensure participant protection.¹ Similar to the H3Africa Initiative, which focuses on African research ethics capacity-building, FERCAP's efforts demonstrate how regionally rooted models can be scaled for global impact.⁴

A prominent theme throughout the conference was the growing recognition of social science research ethics. While biomedical research has long been under rigorous oversight, social science research—especially studies involving vulnerable communities—still faces methodological and ethical gaps. The sessions emphasized the need for culturally validated tools, privacy safeguards, and researcher accountability. This resonates with international discourse on contextual ethics, particularly in low- and middle-income countries (LMICs), where universal principles must be tailored to fit specific socio-cultural realities.⁵ The inclusion of sessions specifically addressing ethics in public health and traditional medicine marked a significant step toward inclusivity and decolonizing research ethics, aligning with calls from UNESCO and CIOMS for more participatory and locally grounded ethical reviews.⁶

Post-approval monitoring and site visits emerged as pivotal strategies to ensure research compliance, especially in light of protocol amendments and serious adverse events (SAEs). The FERCAP conference echoed persistent concerns that Serious Adverse Events (SAEs) are frequently underreported and that post-approval

monitoring mechanisms remain underdeveloped. These issues reflect systemic challenges previously documented, including limited capacity for ongoing oversight and inadequate reporting structures within many IRBs across low- and middle-income countries (LMICs).⁷ The recommendations for mandatory GCP training, updated SOPs, and structured feedback loops are consistent with WHO's 2023 Benchmarking Tools that stress the need for real-time and proactive ethical oversight.¹ These tools also emphasize the importance of transparency and institutional accountability, areas that the conference addressed through dialogue on compensation frameworks, researcher misconduct, and community grievances.

The evolution of bioethics and the challenges posed by emerging technologies—such as AI in mental health research—were central to the plenary and parallel sessions. While the global discourse increasingly emphasizes AI ethics and data privacy, few forums have directly addressed how these topics intersect with human research ethics in LMICs. The FERCAP discussions filled this gap by addressing regulatory uncertainty, lack of preparedness, and ethical tensions in technology-mediated research. Compared to European networks like ALLEA (All European Academies),⁸ which focus on policy harmonization for AI, FERCAP's grassroots perspective provided a more practice-oriented and community-sensitive lens. This positions FERCAP as an important bridge between theoretical ethics and real-world application in diverse regulatory environments.

Finally, the conference reflected strong leadership from the Nepal Health Research Council (NHRC), showcasing Nepal's progress in governing over 60 institutional review committees through digital innovations and localized SOPs. FERCAP's 2024 achievements—including financial sustainability, expanded institutional recognitions, and preparation for its 25th anniversary—indicate a robust and resilient ethical infrastructure. By comparing FERCAP's networked approach to regional ethics governance models like PHREB in the Philippines and NECAST in Thailand, it becomes evident that South-South collaborations are critical for advancing shared ethical principles. The commitment to integrating social science ethics, revising global guidelines, and promoting inclusive participation further sets a precedent for other regions. Future efforts should continue aligning with international standards while ensuring ethical practices remain adaptive, participatory, and culturally relevant.

CONCLUSIONS

The 24th FERCAP International Conference underscored the growing complexity and importance of ethical governance in health research across Asia and the Western Pacific. Key themes—such as enhanced post-approval monitoring, ethics in social science research, responsible use of emerging technologies, and inclusive stakeholder engagement—reflect an evolving commitment to safeguarding participant rights and scientific integrity. The active participation of national ethics bodies, including NHRC's leadership, further demonstrated the strength of regional networks in harmonizing ethical standards while adapting to local contexts. As clinical research landscapes become increasingly decentralized and digitized, ethics committees must remain agile, well-resourced, and adequately trained.

Moving forward, continuous capacity building, integration of updated international guidelines, and fostering South-South collaborations will be essential to sustain progress. The conference reaffirmed that ethical oversight is not just a regulatory function, but a shared responsibility rooted in trust, transparency, and societal benefit. These outcomes provide a strong foundation for FERCAP's 25th anniversary in 2025, reinforcing its role as a global leader in research ethics advancement.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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