

Advancing Research Governance in Nepal: Lessons from the NHRC-ICMR Technical Exposure Visit

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ABSTRACT

The Nepal Health Research Council (NHRC) and the Indian Council of Medical Research (ICMR) established a bilateral collaboration under a Memorandum of Understanding (MoU) signed (January 2021) to foster scientific exchange, capacity building, and health research ethics. NHRC officials comprising research officers, ethics administrators and journal office staff completed an exposure visits to the ICMR headquarters in New Delhi in February 2026. The visit's sessions were centered on ethical practices of ICMR's Bioethics Unit such as the functioning of ethics committees, clinical trial registries, quality assurance protocols, research laboratory standards, and responses to emerging bioethical challenges.

This observational engagement identified operational models of potential relevance to NHRC's mandates. Information was compiled from site visits, institutional documents, and expert presentations, and synthesized narratively into thematic lessons. This report describes observed approaches to ethical governance, digitalization, and quality assurance that may inform the strengthening of Nepal's research governance framework. Digitalization, updated national guidelines, tiered accreditation of research institutions, public engagement, and systematic human resource development were identified as priority areas for strengthening research governance in Nepal.

Keywords: Bioethics; capacity building; ethics committees; international cooperation; technology assessment.

INTRODUCTION

The Indian Council of Medical Research (ICMR) is India's apex body for the formulation, coordination, and promotion of biomedical research. It functions under the Department of Health Research within the Ministry of Health and Family Welfare. The ICMR Bioethics Unit, based in Bengaluru, serves as the national focal point for promoting and safeguarding the ethical conduct of health research in India.¹ In Nepal, the Nepal Health Research Council (NHRC) is the national body responsible for promoting, regulating, and overseeing ethical health research through policy development, ethical review, capacity building, and research grants.²

As part of strengthening South-South collaboration, NHRC officials undertook a visit to ICMR Headquarters in New Delhi, India, from 16 to 20 February 2026. The visit provided a valuable opportunity to learn from India's experience in health research governance, bioethics,

and research regulation. Key areas of the discussion included the National Ethical Guidelines, Department of Health Research governance, Health Technology Assessment (HTA), Clinical Trials Registry, Viral Research and Diagnostic Laboratories (VRDL) network, Fellowships and grants, and research initiatives under ICMR in India.

The delegation also visited several specialized divisions and statutory agencies, including the National Institute of Malaria Research (NIMR), the Central Drugs Standard Control Organization (CDSCO), the Quality Council of India (QCI), and the Indian Institute of Health Management Research (IIHMR).

The visit aimed to enhance scientific exchange, strengthen institutional capacity, improve research governance and regulatory practices, promote health research and bioethics, address emerging ethical challenges, and foster sustained South-South collaboration between Nepal and India.

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METHODS

This paper presents a descriptive report based on narrative synthesis of the author's field notes during a five-day exposure visit by officials from the NHRC to leading research, regulatory, and academic institutions in India. The purpose of the visit was to understand research governance, bioethics systems, research regulation, digital innovations, and capacity-building initiatives and to explore their relevance for strengthening Nepal's health research ecosystem.

Information was compiled from multiple sources, including institutional documents, official websites, presentations delivered by experts, discussions with institutional leaders and technical staff, and observations made during site visits. Detailed notes were maintained throughout the program to capture key practices, operational approaches, and lessons relevant to Nepal's context.

Following the visit, the authors conducted a narrative synthesis of their collective field notes, identifying key thematic areas relevant to Nepal's research ecosystem. Similarly, relevant literature was reviewed to place the findings within the broader global context. The findings are presented as thematic lessons, supported by institutional examples and practical observations, highlighting opportunities to strengthen bioethics capacity, research governance, regulatory systems, and international collaboration in Nepal. The observations presented represent the authors' interpretation of information shared during the visit and do not represent the official position of ICMR or its partner institutions.

Thematic Observation and Policy Implications

The exposure visit provided first-hand insights into India's research governance, bioethics oversight, regulatory frameworks, digital transformation, and institutional capacity-building initiatives. Several major themes emerged from the synthesis of observations, discussions, and institutional documents, reflecting best practices and potential strategies to strengthen Nepal's health research ecosystem (Table 1).

ICMR Model for Strengthening Research Integrity

The exposure visit provided valuable insights into ICMR's approach to strengthening research integrity through ethical governance, regulatory oversight, and capacity building. Discussions highlighted key regulatory frameworks, including the *National Ethical Guidelines*

for Biomedical and Health Research Involving Human Participants (2017) and the *Ethical Guidelines for the Application of Artificial Intelligence in Biomedical Research and Healthcare* (2023). These guidelines demonstrate ICMR's commitment to addressing emerging ethical challenges while promoting responsible conduct of research. The draft operational guidelines on Single Ethics Review, subsequently released in March 2026 and reviewed by the authors, further reflect ongoing efforts to harmonize ethical review for multicenter studies by reducing duplication and improving coordination among ethics committees while maintaining participant protection. Ethical guidelines provide a foundation for ensuring respect for research participants, scientific integrity, and public accountability.³

Equally significant was ICMR's emphasis on education and public engagement. Through digital platforms, including YouTube, webinars, and educational resources, ICMR actively promotes awareness of research ethics and responsible conduct of research among researchers, ethics committee members, students, and the wider community. This approach recognizes that research integrity extends beyond regulatory compliance and depends on continuous education and a culture of ethical responsibility. A study from Egypt reported improved awareness of the responsible conduct of research following an education campaign, and supported the integration of research ethics into academic curricula.⁴ Likewise, previous studies have shown that promoting research integrity requires supportive institutional environments, regular ethics training, effective mentorship, responsible collaboration, and strong research ethics systems.⁵

Strengthening research integrity will require continuous capacity building for researchers and ethics committee members, regular revision of national ethical guidelines, and investment in digital governance infrastructure. Sustained cross-sectoral collaboration between regulators and academic institutions is equally necessary to foster institutional accountability and preserve public trust.⁶

Health Technology Assessment (HTA) for a Sustainable Health Research Ecosystem

The exposure visit provided valuable insights into India's institutionalized Health Technology Assessment (HTA) system and its role in supporting evidence-informed health policy and resource allocation. By evaluating the clinical effectiveness, safety, and cost-effectiveness of health technologies, HTA enables governments to

Table 1. Thematic summary of observed practices and implications for Nepal

Theme	Observed practice	Implication for Nepal
ICMR Model for research integrity	Standardized SOPs and ethical guidelines on AI-based research, Cell and Gene Therapy Products (CGTP), etc.	Develop national SOPs and ethical guidelines for emerging technologies.
HTA development for a sustainable research ecosystem	Institutionalized HTA supports evidence-based technology adoption and health policy.	Establish an NHRC-led HTA unit with multidisciplinary expertise.
Decentralize Diagnostic networks and centralize data	Enhanced laboratory capacities from routine testing to active research to generate empirical data for biological product monitoring, vaccine regulation, and public health emergency preparedness.	Strengthen decentralized laboratories with a centralized national data platform.
Capacity building through Human Resource Development schemes	Structured fellowships, mentorship, and career development programs.	Develop a national HRD strategy and strengthen provincial research capacity.
Research institution for vector-borne disease and community ethics	Integrated laboratory research, genomic surveillance, community engagement, and researcher safety.	Strengthen VBD research, community consultation, and field safety mechanisms.
Quality Accreditation Program for Ethics Committees (ECs)	Implementation of a quality accreditation program for EC, investigators and research sites to enhance oversight efficiency	Establish a tiered accreditation system for ethics committees, investigators and research sites.
Editorial excellence based on a capacity development model	Editorial mentorship, peer-review training, and scientific writing workshops.	Strengthen NHRC journals through editor training and capacity-building programs.
Operational hub for the management of clinical research.	Integrated innovation ecosystem linking researchers, regulators, and industry.	Establish a coordinated national clinical research network using the ICMR 4Ds model.
Strengthening the Regulatory Backbone	Digital regulatory platform, compensation framework, and oversight for advanced therapies.	Strengthen digital regulation, build expertise in advanced therapeutics, and enhance NHRC-DDA coordination.

prioritize interventions that maximize health outcomes while ensuring the efficient use of limited resources.

A key strength of the Indian HTA model is its well-defined governance structure and standardized assessment process involving the Medical Technology Assessment Board (MTAB), regional resource centers, technical appraisal committees, and user departments. A structured workflow, from topic prioritization and evidence synthesis to economic evaluation and policy recommendations, combined with an online topic submission portal, enhances transparency, stakeholder engagement, and timely decision-making.

In the UK, the HTA program provides high-quality research information on the effectiveness, costs, and

broader impact of health technologies, and those findings directly influence decision-making bodies. Likewise, researchers who identify research issues can apply for grants for clinical trials under the HTA program.⁷ Collaborative research through South-South partnerships can enhance HTA by facilitating knowledge sharing, staff exchanges, and resource distribution, with India, China, and South Africa serving as effective models for strengthening HTA domestically.⁸

Decentralizing Diagnostic Networks and Centralizing Data for Public Health Preparedness

India's Virus Research and Diagnostic Laboratories (VRDL) Network demonstrated how decentralized diagnostic services can be effectively integrated

through centralized data systems to strengthen disease surveillance and public health preparedness. The VRDL network is built on three interrelated pillars: expansion of laboratory infrastructure, strengthening of diagnostic capacity, and integration of laboratory research with public health policy across national, regional, state, and medical college levels. This decentralized model not only improves timely access to quality diagnostics but also develops a skilled and sustainable workforce capable of responding rapidly to emerging and re-emerging infectious diseases.

A notable feature of the VRDL network is its emphasis on coordinated data sharing and knowledge exchange. The quarterly VRDL Bulletin facilitates communication among network laboratories, researchers, and policymakers by disseminating information on pathogen distribution, seasonal trends, genomic surveillance, and outbreak dynamics. This integrated approach enables locally generated evidence to be synthesized at the national level, providing timely information to guide surveillance, preparedness, and evidence-informed public health decision-making. The Regional Virus Research and Diagnostic Laboratory at the ICMR-National Institute for Research in Bacterial Infections (NIRBI), West Bengal, further supports this model by providing genomic surveillance, technical mentorship, quality assurance, and capacity building for regional laboratories and medical colleges within its network.⁹

Strengthening decentralized diagnostic laboratories while establishing an integrated national data platform could enhance disease surveillance, outbreak detection, and emergency preparedness. Such a system would facilitate real-time data sharing, improve coordination between laboratories and public health authorities, and generate high-quality evidence for policy decisions. Achieving this vision will require sustained investment in laboratory infrastructure, digital health systems, workforce development, quality assurance, and equitable access to affordable diagnostic technologies.

Nepal is also evolving in this field through expansion of laboratory diagnostics. For example, the National Public Health Laboratory had established microbiology laboratories in 21 provincial and local hospitals across all seven provinces of Nepal with support from WHO for detection and reporting of drug-resistant pathogens at subnational level.¹⁰

Capacity Building through Human Resource Development

A core takeaway was ICMR's systematic investment in developing a skilled health research workforce. Discussions with experts demonstrated that research excellence depends not only on infrastructure and funding but also on continuous investment in people. ICMR's Human Resource Development (HRD) program described to the delegation comprises four streams targeting medical and dental professionals, non-medical researchers, institutional faculty and early-career scientists. These programs provides structured opportunities for fellowships, mentorship, specialized training, and international exposure, helping researchers develop competencies in research methodology, clinical research, bioethics, regulatory science, and emerging technologies.

Another notable observation was the strong emphasis on lifelong learning and mentorship. Capacity building was viewed as a continuous process rather than a one-time training activity, with experienced researchers actively supporting the professional growth of junior investigators. Similar approaches are equally important for strengthening research ethics systems, where well-trained ethics administrators and ethics committee members play a critical role in ensuring efficient, transparent, and high-quality ethical review, particularly in low- and middle-income countries (LMICs).¹¹ Finding from individual capacity-building programs suggest that such investment can promote scientific productivity, innovation, career advancement, and stronger institutional research cultures through mentorship and collaboration.¹² Likewise, long-term investment in research ethics training has significantly strengthened ethical review systems across several African countries.¹³

Research training is most effective for researchers to improve research capacity within team and raise the prominence of research within their organization. As a result, giving continual opportunities to do research would increase return on investment and aid in the retention of skilled staff members.¹⁴

Research Institutions for Vector-Borne Diseases and Community-Centered Ethics

The visit to the ICMR-National Institute of Malaria Research (NIMR) demonstrated how a dedicated research institute can effectively integrate laboratory science, field epidemiology, and public health practice to address vector-borne diseases. NIMR combines advanced research in molecular biology, genomics, and host-parasite interactions with surveillance and

community-based interventions, enabling research findings to be translated into evidence-informed disease control strategies. Its work on genomic surveillance of drug and insecticide resistance further illustrates the value of integrating advanced laboratory technologies into national vector-borne disease programs.

NIMR's approach to ethical governance and community engagement was particularly noteworthy. Before scientific review, research proposals undergo a completeness check against national regulatory requirements, including registration with relevant authorities such as CDSCO and the Department of Health Research. A distinctive feature of NIMR's community-centered governance is its protocol for research involving indigenous and marginalized populations, where prior community consultation through 'Gram Sabhas' (village councils) precedes individual informed consent. This culturally sensitive approach promotes community participation, builds trust, and respects local decision-making while maintaining the principle of autonomy. The institute also recognizes its ethical responsibility toward research staff by ensuring that project budgets include provisions for the diagnosis and treatment of occupational exposures encountered during field research.

Fostering research on vector-borne diseases will require sustained investment in laboratory infrastructure, genomic surveillance, skilled human resources, and institutional research capacity. Although Nepal has collaborated with international partners and aligned research with national disease elimination strategies, limited laboratory infrastructure, inadequate funding, and shortages of trained researchers continue to constrain long-term research capacity.^{15,16}

Accreditation for Strengthening Research Ethics Committees

Observations at the National Accreditation Board for Hospitals & Healthcare Providers (NABH) illustrated how accreditation strengthens the quality, accountability, and credibility of ethics committee. Through certification, accreditation, grading, and independent third-party assessments, NABH promotes compliance with ethical and regulatory standards while safeguarding research participants and enhancing research integrity.

Another notable initiative was *Gunvatta Pathshala*, which supports continuous quality improvement through role-based induction, self-learning modules, Good Clinical Practice (GCP) training, and workshops

for ethics committee members and researchers. The QCI philosophy, "*Ek Yudh Swayam Ke Viruddh*" ("A battle against oneself"), reflects a culture of continuous quality improvement.

Nepal has implemented the Integrated Research Ethics Review Portal (IRERP) to coordinate its 63 Institutional Review Committees (IRCs) standardize ethics review, and strengthen oversight. Introducing a structured accreditation system would further improve the quality and consistency of review.¹⁷ As Shaw has argued, accreditation is most effective when supported by strong governance, appropriate regulation, sustainable financing, and continuous capacity building.¹⁸ Ongoing international efforts to accredit clinical research sites and clinical trial professionals further reinforce the importance of quality assurance in strengthening research governance.^{19,20}

Operational Hub for the Management of Clinical Research

The exposure visit demonstrated India's coordinated approach to managing clinical research through integrated initiatives such as MedTech Mitra, Patent Mitra, and the Indian Clinical Trial and Education Network (INTENT). These initiatives provide researchers with regulatory guidance, intellectual property support, technology transfer, and coordinated multicenter clinical trial networks, creating a streamlined pathway from innovation to implementation. The INTENT network, coordinated through the Clinical Studies and Trial Unit (CSTU), strengthens collaboration among hospitals, medical colleges, researchers, regulators, and industry while facilitating high-quality, regulatory-compliant clinical research. Complementing these efforts, a division-specific funding model organized around four domains (4Ds) – descriptive, delivery, development, and discovery; supports research across the innovation continuum.

Nepal must increase the entire spectrum of research capacity: frequent change of health administrators in key positions at various levels, inadequate financial support from the government, and lack of career opportunities with adequate incentives for the scientist/researcher is becoming a challenge, thereby evolving the situation of brain drain.²¹

Editorial Excellence Based on a Capacity Development Model

The discussions highlighted that scientific journals can

play a pivotal role in strengthening research capacity beyond their traditional publishing function. The Indian Journal of Medical Research (IJMR) has established a structured editorial system supported by experienced editors, technical reviewers, and educational initiatives that help improve the quality of scientific manuscripts. Regular workshops on scientific writing, manuscript preparation, editorial processes, and technical screening equip researchers with the skills needed to publish high-quality research while fostering a culture of scientific excellence.

A key lesson was that journal editors and reviewers can serve as mentors and capacity builders rather than solely as gatekeepers of publication. This approach is consistent with findings by Cheung et al., who describe how journal editors conceptualize their role in capacity building.²²

Strengthening Nepal's editorial capacity through structured training for editors and reviewers, mentorship programs, and closer collaboration among journals, academic institutions, and research organizations could substantially improve the quality, credibility, and visibility of national scientific publications. Such collaboration would also promote research integrity, reduce publication misconduct, and support sustainable journal development aligned with international publishing standards.^{23,24}

Strengthening the Regulatory Backbone

Discussions at the Central Drugs Standard Control Organization (CDSCO) highlighted the importance of a strong, integrated regulatory system in ensuring ethical, transparent, and accountable clinical research. Through the SUGAM digital portal, CDSCO manages the registration, review, and monitoring of clinical trials while facilitating communication among researchers, sponsors, ethics committees, and regulators. The portal also incorporates a digital grievance redressal mechanism, promoting transparency, accountability, and timely resolution of regulatory concerns.

Discussions further highlighted CDSCO's balanced regulatory approach, which combines facilitation of ethical research with effective regulatory oversight and enforcement. A notable feature is its structured framework for determining compensation for research-related injury or death, ensuring participant protection and regulatory consistency. The regulatory system has also evolved to address emerging technologies through dedicated oversight of advanced therapeutic products,

including cell-derived medicinal products, gene therapies, and xenotransplantation. Strengthening an integrated digital regulatory system with transparent approval processes, grievance redressal mechanisms, clear compensation policies, and regulatory oversight for emerging health technologies would enhance participant protection, improve public confidence, and support a more efficient and accountable research environment.

Achieving this will require sustained institutional capacity building, digital transformation, and closer coordination among regulatory authorities, ethics committees, and research institutions.²³

CONCLUSIONS

The technical exposure visit to India's leading research and regulatory institutions, including ICMR, CDSCO, NIMR, NABH, and other partner organizations, provided valuable insights into building a resilient, ethical, and innovation-driven health research ecosystem. The experience reinforced the view that strong research governance is underpinned by robust regulatory systems, continuous capacity building, digital transformation, quality assurance, strategic collaboration, and meaningful public engagement. Key initiatives such as integrated clinical research networks, Health Technology Assessment (HTA), decentralized diagnostic networks with centralized data systems, structured human resource development, and accreditation of ethics committees offer practical models that can be adapted to Nepal's context.

For Nepal, strengthening health research will require coordinated efforts to modernize regulatory and ethical oversight, invest in skilled human resources, foster institutional and regional collaboration, promote research integrity, and build sustainable digital research infrastructure. Enhancing the capacity of ethics committees, regulatory authorities, and scientific journals, together with creating an enabling environment for innovation and high-quality research, will support evidence-informed policymaking and contribute to a self-reliant, ethical, and sustainable health research ecosystem aligned with national health priorities.

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CONFLICT OF INTEREST

The authors declare no competing interest.

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