

## Review Article

# The Role of NHRC in Regulating Health Research Ethics in Nepal: A Narrative Review

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## Abstract

This study aims to chart Nepal's evolution of health research ethics over time and the role of the Nepal Health Research Council (NHRC) in its regulation. This narrative review article mentions the pervasiveness of contract research and the contribution of universities and international organizations in producing data and supporting pilot projects. It further highlights the structural inequalities and limitations of health research in Nepal, including lack of technology, infrastructure, funding, limited access to resources and global scientific networks. It discusses Nepal's emerging regulatory and ethical field, establishing the NHRC and developing ethical guidelines and review committees. The challenges faced by NHRC in terms of capacity and resources and the need to strengthen research ethics monitoring and compliance are also marked. This article also discusses several key challenges and areas of concern regarding research ethics and capacity building in Nepal's health research context. The conflicts arising from defining health research and determining which activities require ethical review are highlighted, especially about programmatic interventions and monitoring and evaluation exercises. The need for comprehensive mapping of health research activities is emphasized as an initial step toward understanding the research landscape. Additionally, issues related to timely ethical reviews, the co-investigator's role, institutional research capacity, data ownership, publication practices, and the ethical considerations of health and development interventions are discussed. It emphasizes redressing these challenges and promoting responsible research practices in Nepal.

Keywords: Ethical review, health research, Nepal, NHRC, research ethics

## Introduction

Health research ethics is the ethical conduct of research in the health field, ensuring that the ethical concerns align with the core values of justice, beneficence, and respect (NHRC, 2015). It focuses on treating humans as test subjects in medical or health research and aims to protect their rights, welfare, and safety.

Unlike other countries in South Asia, research in the health sector in Nepal has a relatively recent history. International collaborative assemblages of aid agencies and universities sponsor most health research activities in the country. Recently, there has been significant discourse

surrounding health sector research and its relevance to policy development. Researchers have delved into the interplay between various types of research and the evidence they produce, aiming to inform policy decisions effectively (Li et al., 2014; Victora et al., 2004). Moreover, particular attention has been given to comprehending the challenges of systematic reviews when applied to the intricate health intervention landscape in developing nations. (Lifsey et al., 2015; McMichael et al., 2005)

A significant portion of the existing scholarship in health sector research in resource-constrained settings has centered around insight into modern pharmaceutical research and development involving human subjects in clinical trials and health experimentation (Schulman, 2011). The ongoing discourse on health research ethics has predominantly emphasized the importance of informed consent, potentially overshadowing other ethical responsibilities that should be considered (Boulton & Parker, 2007).

Hyder et al. (2014) suggests that there is a need for further efforts to explore ethical considerations in countries with low and moderate incomes. The current approach to researching human subjects needs to be revised and more cautious in examining complex health system issues in developing countries (Macklin, 2004). Low-income countries rely heavily on foreign aid to sustain their healthcare systems and service delivery. Research in the health sector is crucial to developing public programs and policies. However, particular economic challenges are brought on by the uneven distribution of resources, reliance on outside finance, and a lack of local capacity to manage and ensure ethical standards in research by these countries (Hyder et al., 2014).

NHRC is the primary governmental body overseeing health-related research. Its pivotal role involves establishing ethical standards and norms and promoting the responsible conduct of research (van Teijlingen & Simkhada, 2015; Victora et al., 2004). Apart from regulating research activities, the NHRC actively contributes to advancing knowledge by generating evidence, publishing research reports and journals, and fostering research capacity among healthcare professionals.

The purpose of this study is to trace the development of health research ethics in Nepal over three distinct periods: the early years (1952–1991), the years that followed the creation of the NHRC (1992–2002), and the years that followed the establishment of the Ethics Review Board (ERB) under the NHRC (2002–2017). This gave us a broad picture of the country's health research activities, focusing on health experimentation, regulation of health research ethics, and the function and contribution of NHRC in this area.

### **Methods and Materials**

The study design is a desk review type, including narrative review methods aiming to identify and summarize what has already been published in the area of health-related research ethics in Nepal. It followed a 'writing in an easy-to-read format and allowing for a wide range of perspectives on a topic' (Green, Johnson, & Adams, 2006), including examining existing arguments, evaluating previous research on health research ethics in Nepal, and identifying gaps or whereabouts in the area. The information used to write this article was gathered from sources

such as Google Scholar, PubMed, Nepjol, and manual searches of relevant literature references. The keywords used for the search include research ethics, health research, Nepal Health Research Council, ethical review and a combination of these words where necessary.

## Results and Discussion

### The Political Economy of Health-Sector Research in Nepal

Nepal's interest in scientific research is relatively new, unlike other South Asian contenders (Worth & Shah, 1969). The emergence of health research in Nepal can be attributed to the assistance provided by the United States, which commenced in 1951. While promoting Nepal's development, the United States Operations Mission (USOM), later known as the US Agency for International Development (USAID), confronted a significant hurdle of having insufficient comprehensive data. A 1958 USOM publication emphasized the necessity for more dependable health statistics, which posed challenges in accurately evaluating health conditions and their pertinence to the complexities of resource exploitation and development (Boch-Isaacson, 2001).

The USOM initiated Nepal's initial systematic research endeavor in 1952, which involved surveying malaria. This research project was developed with the country's efforts to control and combat malaria. The University of Hawaii and the Thomas A. Dooley Foundation provided help for the first Nepal Health Survey, conducted in 1965–1966. Its primary goal was to provide baseline quantitative data to enable the Ministry of Health to plan and gauge the success of Nepal's upcoming health activities (Worth & Shah, 2021). During its initial stages, USAID started utilizing sector assessments, pilot studies, and Peace Corps Volunteers (PCVs) for active involvement to enhance project design and implementation. An anthropologist who studied health development in the 1970s suggested that the government and donor organizations produce a wide range of in-depth reports, including background papers, feasibility studies, yearly reports, progress reviews, and project proposals. (Justice, 1986)

In the past six decades, health research in Nepal has encompassed a diverse range of areas. It ranges from purely biological research to producing data for intervention programs in the larger health field. With their assistance and funding, partnerships between local and international organizations, universities, and humanitarian groups have continued to produce evidence for programmatic interventions (Harper, 2014). These collaborations and institutional structures play a crucial role in generating evidence and providing virtual support networks for scaling up pilot projects successfully. Monitoring research initiatives in Nepal, particularly those that produce data for programmatic interventions, might be challenging. This is mainly because not all research activities are registered with the NHRC, and there is no standardized database or precise definition of health research.

To effectively preempt challenges overseeing research endeavors, NHRC must accurately understand the quantity and nature of research activities within the health sectors. Numerous instances exist where intervention lies at the nexus of Nepal's programmatic ambition and health research. We may further explain by looking at the following examples of manifestations (Khanal et al., 2018).

Between 1988 and 1990, the Nepal Nutrition Intervention Project Sarlahi (NNIPS) received funding from USAID for a Vitamin-A capsule distribution project in the Sarlahi district. This initiative was carried out through collaboration between Johns Hopkins University and the National Society for the Prevention of Blindness in Kathmandu. A community trial encompassed 28,630 children aged 6-72 months in rural Nepal. The trial was designed to uphold rigorous scientific standards using a randomized, double-masked, and placebo-controlled approach (West et al., 1991). Insights gleaned from this study and findings from another research endeavor supported by USAID on Vitamin-A (Daulaire et al., 1992) played a pivotal role in implementing the 'National Vitamin-A Program' in Nepal (Harper & Society, 2002).

Similarly, individuals with limited training among the cadre of health workers demonstrated a capacity to manage childhood pneumonia effectively, a substantial contributor to child mortality among those under five (Pandey et al., 1991). These favorable outcomes prompted Nepal to integrate a community-based element into the national Acute Respiratory Infection (ARI) control program and extend the involvement of Female Community Health Volunteers (FCHVs) in administering antibiotics. A technical working group with representatives from the government, UNICEF, WHO, USAID, and John Snow Inc. was established in 1993 to pursue this program (Dawson et al., 2008).

Nepal has seen the establishment of various non-governmental organizations (NGOs) and private research companies specializing in health systems research, except a small number of medical education institutions. These organizations primarily work with the government and bilateral, multilateral, and private philanthropic groups under short-term subcontracts (Swanson et al., 2015). A distinct culture of contract research has taken root, particularly in health systems research. This culture comprises widespread participation by organizations and individuals in quick contracts with sponsors, primarily international non-governmental organizations (INGOs) and bilateral and multilateral entities. These contracts typically involve activities such as conducting feasibility studies, evaluations, baseline surveys, and end-line surveys.

In most cases, the commissioning sponsor provides initial research frameworks, imposing tight schedules that offer minimal or no dedicated time for publication writing (Pratt & de Vries, 2018; Swanson et al., 2015). Occasionally, sponsors also dictate factors like the sample size and selection of study locations. Beyond influencing the research design, sponsors frequently monitor the study's progress and oversee the eventual publication of findings. It is common for sponsors to retain data ownership, leading to restricted ownership for sub-contractors involved in the research.

The names of researchers are not consistently featured as authors on the initial pages of the research report; instead, they are generally acknowledged within the acknowledgment section. Although formal contracts are awarded through a competitive method, building "trust" between sponsors and contract research businesses typically depends on pre-existing working associations, serving as the pivotal factor in contact allocation. Moreover, the distribution of research findings and the alignment of research with specific policy domains are contingent upon these personalized networks (Angell, 1997; Pratt & de Vries, 2018).

As an illustration, consider an operational study conducted between 2005 and 2007 in the Banke district, focusing on the viability of distribution of misoprostol, referred to as "Matri Suraksha Chakki" locally in Nepali, through Female Community Health Volunteers (FCHV). This study was carried out under the auspices of the USAID-supported Nepal Family Health Program (NFHP). During this research initiative, interacting, dedicating time, and involving senior government officials through the program's framework facilitated a channel through which government policy is influenced.

Similarly, the scarcity of research funding within the local context compels local resources and institutions to actively seek collaboration with research partners from more affluent regions, often involving international research organizations and universities. These collaborations are shaped by the resources and partners available in these relationships, the practical aspects of conducting research, and establishing networks. Concurrently, there is a prevailing sentiment that local research organizations and researchers have transitioned into better active research participation. Instead of playing the role of "sleeping partners," Northern partners continue to take the lead in identifying research concerns and creating research questions and methodology designs to organize the overall research project.

Despite having knowledge of and involvement in study protocol design, the requirement for a substantial understanding of scientific Discussion often limits the participation of researchers and research organizations based in Nepal to offering minimum input on the protocol. Ongoing challenges persist in cultivating research capacity within Nepal and building institutional capabilities for research-related endeavors. One notable challenge pertains to the frequent staff turnover within the organization (Swanson et al., 2015). Nepal's political and economic development landscape has led to a hierarchical compensation structure. Proficient individuals can transition between different institutional spheres to negotiate higher remuneration. Furthermore, governmental institutions are affected by explicit political influences, resulting in personnel changes coinciding with shifts in government. These interferences are also observed in research-related activities, where direct intervention can impact the composition of research teams and the research process itself (Regmi et al., 2017; Samuels et al., 2017).

Furthermore, similar to other low-income countries, health research in Nepal is carried out within a context of structural inequalities characterized by limited technology, inadequate infrastructure, and insufficient funding. For instance, the availability of state-of-the-art laboratory equipment is crucial. However, it often depends on external grants, as many sponsors must cover overhead costs. Additional challenges arise due to local constraints even when the necessary equipment is obtained. These include the unavailability of reagents in local markets and difficulties in transportation caused by the challenging terrain and inadequate infrastructure, such as poorly maintained roads prone to damage during the monsoon season. These factors further contribute to the complexities of conducting health research in Nepal.

Various challenges, including insufficient internet connectivity, constrained availability of scientific journals, financial constraints for conference participation, and stringent visa regulation in wealthy nations, collectively create barriers that prevent researchers from

accessing global resources. While local researchers are frequently sought after as consultants and are engaged in numerous research projects, their mobility between domestic and foreign organizations or their recruitment by external institutions hinders the consistent growth of institutional research capacity within Nepal. As highlighted by Vetter (2006), these factors are obstacles to the sustainable advancement of research capabilities at the institutional level in Nepal.

### **Regulatory and Ethical Field in Emergence**

The Nepal Medical Research Committee, housed inside the Ministry of Health and founded on April 15, 1982, oversaw medical research in Nepal before 1991. Numerous internationally formed or supported research programs, frequently featuring junior partners or consultants from Nepal, obtained research and ethical clearances from review organizations in other countries, obviating the need for approval from Nepal. Before NHRC was established, the health secretary managed local research assessments in Nepal. However, the political landscape in Nepal underwent significant shifts following the 1990 revolution, resulting in the restoration of the democratic process. These political changes also transformed a government institution, including alteration to research oversight and review procedures.

The NHRC was established in 1991 through a parliamentary act. Its primary objectives are to foster a research culture and to oversee the review, regulation, and approval of health-related research proposals. The Ministry of Health provides the NHRC's funding (Khanal et al., 2018). The NHRC's Executive Board consists of politically-employed members. Among them, seven are Cabinet-nominated. At the same time, the remaining five represent various institutions, such as the Committee of the Institute of Medicine (IOM) and the Chairperson of the Nepal Medical Council (NMC). The Council's executive leader may be the member secretary or the chairperson (Khanal et al., 2018; Whelpton, 2005).

In 1991, health-focused research underwent evaluation by the Scientific and Ethical Committee at the NHRC. Moreover, the subsequent refinement of the process led to the initial creation. National Guidelines for Ethical Review, issued in 1995, received official endorsement from the ERB of the NHRC in 2022, coinciding with the establishment of the ERB in its current structure during the same year. The ERB is constituted through nomination by the Executive Committee of the NHRC (Khanal et al., 2018).

The creation of ethical guidelines, the foundation of the ERB and Institutional Review Committees (IRCs), an increase in the number of research proposals submitted for honest review, and the availability of research ethics training for medical professionals are all examples of progress made in Nepal's field of research ethics over time. However, it is essential to note that not all research conducted in Nepal undergoes ethical approval (van Teijlingen & Simkhada, 2015). Specifically, research conducted by students and faculty members not affiliated with IRCs and health research in disciplines such as social sciences and technology often bypass the ethical review process. Researchers commonly need to seek clarification regarding the acceptance of ethical approval from their study sites. It is crucial to raise awareness among researchers and research organizations about the importance of obtaining ethical approval for their studies.

Enhancing the monitoring of research ethics and compliance is a crucial aspect that requires strengthening. However, the current context poses challenges for the NHRC (Nepal Health Research Council) due to its limited network and the restriction of IRCs to monitor internal research only. There are diverse opinions on the functioning of the NHRC. One significant criticism of the Council is its time to review proposals. While several organizations recognize advancements from the past, when the Council may take up to three months to study, they continue to think that the NHRC needs more capacity and personnel to move its work along more quickly. Given its predominant representation of medical professionals, the NHRC also needs more human resources and expertise to review various research proposals in the health sector effectively. As a result, the NHRC seeks the assistance of independent consultants to conduct reviews (Khanal et al., 2018; van Teijlingen & Simkhada, 2015).

The NHRC faces the challenge of handling a growing number of research applications. To address this, the NHRC has delegated some of its responsibilities to other research-oriented entities. IRCs have been established with the proliferation of medical and nursing programs and related research. IRCs operate within the institutions but must adhere to the NHRC guidelines (NHRC, 2011). The ERB of NHRC is responsible for approving these IRCs, and the IRCs must provide biannual reports on their activities. The IRCs can examine and support research projects that are internally financed or ones that students do as part of their degree programs (Sharma et al., 2016). However, authorization must be obtained directly from the NHRC's ERB for clinical trials, multi-sited studies, externally sponsored research, and national or international research. In addition to the existing guidelines, there is a need for a greater understanding of how these IRCs function and carry out proposal reviews (Council, 2011; Khanal et al., 2018).

### **Redressing the Issues of Health Research Ethics**

The situation in Nepal highlights an apparent discrepancy between the concept of health research subject to NHRC ethical assessment and initiatives for quality improvement, monitoring, and evaluation, for example, which are not directly related to health research. Although this problem is not specific to Nepal, it gains particular significance due to the prevalence of health research-integrated programmatic interventions and studies assessing the viability and effectiveness of specific service delivery models and various monitoring and evaluation activities (such as program review and assessments). To tackle this challenge, an essential initial step involves conducting a comprehensive mapping exercise to create an inventory of health research activities. This effort would offer a more precise comprehension of the overall research landscape in the country.

The NHRC encounters challenges in conducting ethical reviews promptly due to limited resources and the frequent changes in government, which impact the composition of the NHRC board. These circumstances result in delays in the review process. Furthermore, there is a demand for enhanced expertise within the NHRC to manage diverse research categories effectively. Short-term research project often needs more review time since it is not customarily integrated into the proposed timeline by sponsors. Another potential concern pertains to members' availability on the ERB, as at least six of the eleven members must be present during ERB meetings to grant study approval.

Thirdly, the NHRC has implemented a mandatory regulation requiring the inclusion of a Nepali co-investigator in the research application because many research studies involve foreign investigators. Although this policy aims to increase local capacity, how well these procedures will encourage co-investigators to participate actively is still being determined. In certain instances, co-investigators might be added merely to fulfill the policy requirement without truly engaging as genuine research celebrators, thus impeding the cultivation of a robust research culture. Hence, a more comprehensive approach would prove advantageous, encouraging co-investigators to allocate dedicated research time and integrate their research and publication as career progression and advanced criteria.

Furthermore, research collaboration has frequently emphasized enhancing individual capabilities, often overlooking the development of institutional and organizational research capacities. This tendency is observable in the movement of researchers between organizations and the common practice of recruiting skilled researchers from other institutions. The relationship between sponsors and subcontractors is characterized by inequality, with subcontractors having limited control over the overall research design and the utilization of research findings. Local research organizations rarely receive direct money from sponsors while playing a substantial subcontracting role in completing on-the-ground duties. Additional resources are urgently needed to address the indirect costs associated with research initiatives fully. This situation has implications for data ownership and limited funding for sub-contracted budgets, leaving scholars with insufficient time to focus on research publications.

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Responsibility for publishing the results of studies is still an issue that has to be resolved. Authors from low-income nations occasionally publish the results in international journals with affordable open access. In many instances, the results remain unknown and unpublished. To address this problem, it could be helpful to include explicit provisions in research authorization



that require publication in Nepalese journals, foreign journals with open access, and other relevant publication venues. This would help ensure broader dissemination of research findings and increase accessibility to local and international audiences.

### **Conclusions and Implications**

Addressing the research capacity gap in Nations with moderate to relatively low economic status, like Nepal, is a significant challenge in global health. The WHO Director-General highlighted in 1998 the necessity for a substantial increase in capacity building to improve health and reduce poverty in developing nations. While the function of Nepalese research institutions has changed, moving from the mere implementation of pre-designed research to active research partnerships, it is crucial to gather more evidence to determine if this shift is genuinely changing the dynamics. The unequal playing dominant within contract research and global investigation collaborations within relatively low economic countries raises broader questions that extend beyond the scope of the ethics board and require comprehensive examination.

Many research projects in underdeveloped economies focus on experimental programmatic interventions. These interventions are typically supported and carried out by shared efforts involving international aid agencies, policymakers, NGOs, and research institutions. Given their significant role in reforming policies and programs, there is a need for increased public accountability and a more comprehensive understanding of the ethical considerations surrounding health and development interventions. To ensure ethical actions in health and development, it is imperative to broaden the definition of ethics to include these components. In Nepal, health research ethics are constantly changing. To guarantee that research conducted in the nation complies with the highest ethical standards, researchers and institutions must keep up with the most recent rules and regulations issued by the NHRC.

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### **Authors' Contribution**

The article was conceived and written by AA. BA, SD, HA, and AK assisted in the literature review and discussion of the article. The paper was edited by BA, who also communicated with the publication processes. The final version that will be published has the consent of all authors.

### **Conflict of Interest**

The authors declare no potential conflicts of interest regarding this paper's review, writing and publication.

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