

Capacity Building at Nepal Health Research Council for Ethical Research

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Since the establishment of Nepal Health Research Council (NHRC) by an act of parliament in 1991, it is mandatory that all research related to health must get approval from the council.¹ However, the act does not specifically mention the process by which the approval is to be granted. To address this gap, the council initially formed the two committees to review the technical and ethical aspects of the studies and submit their recommendations to the executive committee for final decision. The researchers and reviewers both had to search for resources to guide them about what constituted a right way of conducting research involving human participants. In response to this need, the NHRC developed a very brief guideline for research review in 1995 A.D. Which functioned as a prescriptive document for researchers. However, this guideline was created without wide consultation or discussion. Recognizing the need for broader input, the NHRC mobilized resources to organize a consultative meeting in Kathmandu, bringing together subject experts and ethicists. This meeting led to the formation of an editorial committee tasked with drafting national ethical guidelines for research. The first set of national ethical guidelines for health research was published in 2001 A.D., marking a significant milestone. These guidelines facilitated the formation of the Ethical Review Board (ERB), which consolidated the previously separate technical and ethical review committees into a single board. Since then, the NHRC has made substantial progress in refining its guidelines, revising them regularly to address emerging challenges and align them with international standards. To enhance its capacity for reviewing research proposals from both ethical and scientific perspectives, the NHRC has invested in building physical infrastructure, developing human resources, and incorporating information and communication technologies.⁷ These efforts have strengthened the NHRC's ability to oversee health research in Nepal, ensuring that it meets both national and international ethical standards.

The overall aim of these activities is to promote ethical research practices. These efforts have demonstrated that NHRC is committed to ensure that health research conducted in Nepal is carried out in compliance with ethical principles and guidelines laid down for the purpose of protecting the rights, dignity and well-being of the research participants as well are scientifically valid and credible.^{1,2} As a result of these efforts, ERB of NHRC has been accredited by Forum for Ethics Research Committee of Asia Pacific (FERCAP) since 2019. NHRC's commitment for promoting ethical research is essential for maintaining public trust and ensuring that research contributes positively to society.

The initiatives taken by NHRC to promote ethical conduct of research in Nepal can be detailed as follows:

Development of Guidelines: The NHRC has developed comprehensive guidelines that offer a clear framework for researchers, reviewers, and ethics committees to ensure that research is conducted responsibly and ethically. Before the establishment of the NHRC, and even in its early years, there were no specific guidelines tailored to different types of studies, including those involving animal research. The first National Guidelines were published in 2001 and since then there have been periodic revision of these guidelines in 2011, 2019 and 2022.^{3,8} Other guidelines included, Guidelines for Institutional Review Committees (IRCs) for Health Research in Nepal 2005 and 2016, and National Guideline on Clinical Trials with the Use of Pharmaceutical Products 2005, Ethical Guidelines for the Care and Use of Animals in Health Research in Nepal 2005. These guidelines have since served as a cornerstone for ethical conduct in research across Nepal, providing essential guidance for a wide range of studies.

Establishment of Ethics Review Board (ERB) and Institutional Review Committees (IRCs): The Ethical Review Board (ERB) of the NHRC serves as the central

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body for reviewing and approving research protocols at the national level. As research activities expanded with the growing number of academic and healthcare institutions, the workload on the ERB increased. In response, the NHRC developed and published different guidelines and expanded the regulations activities through the Institutional Review Committees (IRCs). Currently, 60 IRCs have been established and are actively reviewing and approving the research protocols in accordance with the National Ethical Guidelines for Health Research in Nepal. The decentralization of the ethical review process to these institutional committees has significantly reduced the burden on the NHRC's ERB, as demonstrated by the ERB's database from 900 to 700. However, research involving high risk, multiple centers, external sponsorship, or international researchers must still undergo the ERB's review process.^{3,4}

Training of Researchers and Members of Ethics Committees: Education and training are integral to promoting ethical research. NHRC offers training programs to enhance the understanding of ethical principles among researchers and members of the research review committees.⁴ The training program includes presentation and discussion on background information on ethical theories and principles, mechanisms to implement those principles in practice, elements of responsible conduct of research, importance of ensuring voluntariness in participation in research after the participant had been informed of the research process and the participant's role and possible risks or benefits of participating in the activity.⁵

Monitoring of research projects: NHRC has implemented a system to monitor the research projects to ensure that these are being conducted according to the approved protocol and they adherence to ethical and scientific standards, particularly focusing on different risk categories. This oversight is crucial for addressing any ethical issues that arise during the research process.^{1,3}

During such monitoring visits, several challenges in ensuring ethical conduct of research are identified. A significant challenges involves the process of obtaining informed consent. While protocols must comply with the requirement to fully inform participants about the research process, their involvement, potential risks and their right to withdraw voluntarily, it has often been observed that participants are not fully aware of their rights. Furthermore, participants tend to have limited information about the research itself. In contrast, the research teams frequently report using tools, such as test of understanding to ensure that participants

comprehended the language and content of the consent forms. This highlights a critical gap between researchers' communication and participants' understanding. To address these issues, further efforts are needed to enhance communication strategies and bridge this gap, ensuring that participants' rights are respected and they are truly informed during the consent process.

Requirement of journals: The requirement by scientific journals for researchers to submit evidence of ethics approval from a recognized ethics review committee has been instrumental in ensuring that every published article undergoes ethical scrutiny. This process not only upholds the integrity of research but also plays a critical role in the dissemination of findings. By mandating ethical review, journals contribute to the transparency and accountability of research, ensuring that studies are conducted responsibly and in accordance with ethical standards. Consequently, when research findings are disseminated, whether through journals, conferences, or public platforms, stakeholders can have confidence that the research adhered to ethical guidelines, thus enhancing the credibility and impact of the shared knowledge. This linkage between ethical review and dissemination fosters greater trust in the research outcomes among policymakers, practitioners, and the public, encouraging the application of findings in real-world settings

Establishment of a complaint handling subcommittee: The establishment of a complaint-handling subcommittee by the NHRC reflects a growing recognition of the need to address issues arising from research misconduct, whether from participants, researchers, or team members.⁹ While complaints are increasing, the capacity to effectively handle these grievances remains limited, signaling an area in need of further development. Research misconduct, including ethical violations such as insufficient informed consent or data manipulation, undermines the integrity of scientific inquiry and avoiding ERB/ IRC approval.

Given the pivotal role journals play in disseminating research, it would be beneficial for both NHRC and publisher to collaborate on developing comprehensive guidelines for managing such complaints. This joint effort could create a framework that strengthens the ethical oversight of research, ensuring that complaints of misconduct are adequately addressed, thereby reinforcing the credibility of published findings and protecting the rights of all involved.

Future steps: The Nepal Health Research Council (NHRC) is at the forefront of promoting ethical research in Nepal and this task is being carried out through Ethical Review Board which is supported by permanent secretariat manned by research officers and support staff. However, the workload of the secretariat is increasing day by day, yet it faces significant challenges in administration and smooth operation. Some of the challenges include a lack of skilled manpower, frequent staff turnover, insufficient training and skill development, and inadequate mechanisms to prevent manpower drain. There is a need of a specific plan to further strengthen the capacity within NHRC. The following steps are highlighted for further strengthen the capacity of the NHRC:

- a. Adequate and appropriately trained human resources in the secretariat and adequate infrastructure to manage increased workload. Capacity building initiatives, such as continuous professional development and skill enhancement, are essential for implementing harmonized procedures across ethics committees. This will contribute to improved research governance and enhance the overall efficiency and effectiveness of the ethical review process
- b. Development of an integrated online electronic database system to harmonize the ethical review process as it plays a vital role in record-keeping, monitor IRC activities, and streamline communication. Such a system would facilitate the submission, review, approval, and monitoring of conduct of research and improve data accuracy, and facilitate better communication and collaboration and enhance transparency and accountability and data accuracy. Furthermore, it would support the dissemination of ongoing and completed research and promote data sharing, ultimately strengthening NHRC's research oversight.
- c. The development of both basic and advanced online training courses, along with case studies to guide reviewers, will enhance continuous professional development and ensure consistency in the application of ethical review standards. Comprehensive training programs on research ethics, informed consent processes, research methodologies (qualitative and quantitative), proposal development, data analysis, and report writing should be regularly conducted, targeting early-career researchers, ethics committee members, and faculty at both central and provincial levels. Additionally, NHRC should emphasize the development of academic courses on bioethics, such as the master's program initiated in collaboration with Kathmandu University. Provincial grants should support these initiatives to build research capacity nationwide.
- d. Many IRCs have been accredited by NHRC to review and approve certain types of research conducted by their faculty, students and staff. However, the capacity of those IRC varies significantly. Strengthening the capacity of those IRCs through capacity-building, and resource allocation will enhance their ability to review research proposals effectively and uphold ethical standards. NHRC need to have a robust training program for IRC members to ensure that they are well- equipped to handle research proposals.
- e. Establishing a roster of subject experts willing to contribute to timely reviews of research proposals and articles would streamline the review process and ensure that specialized expertise is available when needed. This mechanism would enhance the quality of ethical reviews while facilitating prompt decision-making
- f. To ensure research is conducted according to approved protocols, additional human resources are needed to monitor ongoing studies, particularly those classified as high-risk or sensitive. Continuous oversight is crucial to maintaining compliance with ethical standards and safeguarding the integrity of the research process
- g. The finding of the research is reported through lay language publications and scientific publication that adhere to ICJME guidelines, practically concerning authorship and ethical integrity. A collaborative mechanism between journals and NHRC could ensure that research published is credible and free from plagiarism and other forms of misconducts. This oversight is increasingly important, given the rising number of complaints against authors. A stronger collaboration between NHRC and journals would further ensure the credibility of research publications and address misconduct proactively.
- h. Advocacy for research regulation and governance at all levels is necessary to create a supportive environment for ethical research. This includes engaging with policymakers, funding bodies, and the public to raise awareness of the importance of

CONCLUSIONS

The Nepal Health Research Council (NHRC) has made significant strides in capacity building through its provincial expansion, IRC accreditation, training initiatives, national and international representation, and the development of an online system for ethical review. These efforts have led to a noticeable increase in research proposals submitted for ethical review. However, with the rapid evolution of health research—driven by new technologies / artificial intelligence, expanding clinical trials, and global collaborations—the NHRC must continue strengthening its capacity to meet the growing demands for ethical oversight, particularly in clinical trials and biomedical research.

Moving forward, capacity building should remain a key priority. Continued collaboration with international partners, training for ethics committee members, and investment in digital infrastructure are critical. With these efforts, the NHRC can solidify its role as a leader in ethical health research in Nepal, ensuring the advancement of science while upholding justice, beneficence, and respect for all research participants.

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