J Nepal Health Res Counc 2025 Jan-March; 23 (66):21-24

Nature of Research Proposals Submitted to Institute of Medicine Institutional Review Committee: A Retrospective Review

Mohan Raj Sharma,[1] Lava Shrestha,[1] Kanchana Bali,[1] Ashish Tiwari,[1] Om Prakash Bhatta[1]

[1]Institute of Medicine, Tribhuvan University, Teaching Hospital, Maharajgunj, Kathmandu, Nepal.

ABSTRACT

Background: Efficient evaluation of research proposals is crucial for ensuring ethical standards and scientific rigor in healthcare. This study aims to analyze the proposals submitted to the Institutional Review Committee of the Institute of Medicine to determine the trends in health-related research conducted in a major institute.

Methods: This is a retrospective review of research proposals submitted to the Institutional Review Committee of the Institute of Medicine from May 2019 to April 2021. The analysis focused on the institutional/departmental affiliation of investigators, gender of the principal investigator, funding sources, ethical issues, types of proposals, and research design.

Results: Out of 769 proposals submitted, seven were rejected (acceptance rate of 99.1%). There was a steady increase in the number of submissions over the study period. Descriptive cross-sectional studies were the most frequent 630 (82.6%) followed by randomized controlled trials. More than half [403, 52.9%] proposals were related to health promotion. The clinical departments contributed 443 (58.1%) submissions. Males outnumbered females (54.2% vs 45.8%) and only 53 (7.0%) were funded.

Conclusions: Cross-sectional studies with a focus on health promotion were the most common submissions for ethical approval at the IOM. Policymakers in our institute and other institutions can use this research to set priorities for promoting research.

Keywords: Ethical review; institutional review board; researchers; research proposal.

INTRODUCTION

Research proposals in Nepal must undergo review by the Institutional Review Committee (IRC) or the Ethical Review Board of the Nepal Health Research Council (NHRC) before recruiting research participants.[1] This process ensures responsible conduct of research. The IRC's primary objective is to safeguard human subjects' rights and welfare while adhering to relevant laws, regulations, and international standards.[2,3] It is important to ensure fair and unbiased procedures and timely decision-making.[4]

The IRC of the Institute of Medicine (IOM) was established in 2008 with a mandate to review and oversee all clinical research conducted by IOM faculty, students, and staff, as well as research conducted by external researchers within the institute's premises.

Analyzing submission trends helps identify IRC's workload, resource allocation, and potential gaps in research domains, study designs, and ethical considerations.

This study aimed to analyze research proposals submitted to the IOM-IRC between May 2019 and April 2021, focusing on research design, investigator demographics, and research topic areas, to identify key trends and patterns.

METHODS

After obtaining approval from the IRC of the IOM (approval number #474(6-11,E2), data collection commenced in in May 2021 to June 2021. For this retrospective record

Correspondence: Ashish Tiwari, Institute of Medicine, Tribhuvan University, Teaching Hospital, Maharajgunj, Kathmandu, Nepal. Email: ashish.ancz@gmail.com, Phone: +9779840011243.

review, we examined the proposals that underwent evaluation by the IRC from May 2019 to April 2021 of the IOM in Kathmandu, Nepal, along with the decisions reached. A pro forma was used to record the variables of interest. Confidentiality was strictly maintained throughout the research process. All proposals submitted during the study period were eligible for analysis. Incomplete submissions were excluded.

During the study period, we examined all proposals for the investigators' affiliation with the institute/department, specialty (clinical, basic science, public health, and nursing), gender of the principal investigator, funding, ethical issues, type of proposal (therapeutics, diagnosis, prognosis, or health promotion), and research design. Additionally, we collected information on the type of review conducted by the IRC (exempted, expedited, or full board) and the outcome of the proposal after review (accepted or rejected).

The aforementioned study variables were obtained from paper files and the IRC's database. Data were entered into IBM SPSS Statistics version 25, and descriptive statistical analysis was performed to determine the frequency and percentage of the data.

RESULTS

During the study period, the IRC of IOM received 769 proposals for ethical evaluation. Out of these, 762 (99.08%) proposals were accepted by the IRC of IOM, while 7 were rejected. Among the principal investigators, 413 (54.2%) were male, and 349 (45.8%) were female. Only 79 (10.4%) PIs were from outside IOM, while the remaining 683 (89.6%) were from IOM. Among the total number of approved proposals, (708) 93% were not funded, while (54) 7.0% received funding from institutional grants, NGOs, and INGOs.

Table 1. Data regarding the design of the research proposal.

Design of proposal accepted	Number of proposals
Cross-sectional descriptive	630(82.6%)
Cross-sectional analytical	75(9.8%)
Randomized controlled trials	32(4.3%)
Case-Control	17(2.3%)
Quasi-experimental trials	5(0.6%)
Cohort	3(0.4%)

As shown in Table 1, the commonest research designs were cross-sectional descriptive studies (630, 82.6%) followed by cross-sectional analytical studies, case and control studies, cohort studies, randomized controlled trials, and quasi-controlled trials respectively.

The proposals accepted by the IOM IRC were categorized based on the researchers' specified outcome of interest. The highest number of proposals were related to health promotion (403, 52.9%), followed by prognosis, diagnosis, and therapeutics, respectively. (Table 2)

Table 2. Proposals based on the outcome of interest as specified by the researchers. (n=762)

Accepted proposal related to	Number of proposals
Health Promotion	403(52.9%)
Prognosis	149(19.5%)
Diagnosis	140(18.4%)
Therapeutics	70(9.2%)

Regarding specialty-wise participation in research, the highest number of researchers were from clinical subjects, accounting for 443 (58.1%). About one-fifth (138, 18.1%) researchers were from nursing, while public health and basic science accounted for 99 (13%) and 82 (10.8%) respectively. (Table 3)

Table 3. Specialty Wise Distribution.

Specialty	Number of proposals submitted
Clinical subjects	443(58.1%)
Nursing	138(18.1%)
Basic sciences	82(10.7%)
Public health	99(13.1%)

Likewise, 19 (2.5%) studies were for drug trials and 2 (0.3%) were for vaccine trials. Regarding the ethical clearance of the proposals submitted, 730 (95.8% had no issue while 32 (4.2%) proposals were forwarded to NHRC for ethical clearance.

DISCUSSION

IRCs are indeed a double-edged sword. On one hand, they are responsible for procedural justice, the elimination of bias, pro-science sensitivity, and the protection of human rights. On the other hand, they are often viewed as hurdles to conducting scientific research.[4-6] Nevertheless, the need for an ethical review is indisputable, as it ensures that the institution where the research is being conducted remains legally bound.[7] Many mainstream journals will not process an article unless it is approved by an IRC.

Male researchers were in the majority compared to female researchers. This is in congruence with a previous study by Hyder et al. in developing countries, which showed a similar demographic distribution in institutions across developing countries.[8] The research proposals originated from the Institute of Medicine itself. This is because of the mandate of IOM IRC, which includes students' thesis proposals, and partly due to accessibility. A study by Van Teijling et al. stated how ethical approval may not be sought by researchers from developed countries.[9] This has been attributed to many factors, especially the assumption that developing countries may not have a working ethical review system.[9-11]

The highest number of research proposals belonged to clinical subjects, especially for diagnosis, treatment, and prognosis. However, this does not mean that other disciplines are excluded. Several proposals have been seen from nursing and basic sciences as well. Research proposals accepted by an institutional review committee are influenced by the culture and leadership of their institution.[5,12]

Funded large-scale researches are gaining momentum in Nepal, partly due to the collaborative nature of research and partly due to the establishment of many government organizations, such as University Grant Commissions, which provide funds. But our finding shows otherwise since most studies were observational studies, conducted by postgraduate students as their theses. Research sponsors are also enthusiastic about conducting research in low to middle-income countries, as they are comparatively less expensive and qualified participants are more readily available. [13,14]

In our study, we reviewed research proposals that encompassed case-control studies, cohort studies, and clinical trials, among which cross-sectional descriptive studies emerged as the most prevalent type.

Studies on research proposals submitted to the Nepal Health Research Council revealed that non-communicable diseases (n=150; 15.90%) were consistently prioritized, followed by reproductive health and communicable diseases. Quantitative research accounted for more than two-thirds of all the years. More than half of the approved proposals were for academic purposes (610, 64.69%). These studies also noted a steady increase in the number of research proposals over time.[15,16]

One of the major strengths of this study is that it provides a comprehensive analysis of a significant number of research proposals submitted to the IOM-IRC over two years. By examining a diverse range of proposals, the study provides a reliable and generalizable understanding of the research landscape within the institution. Furthermore, the inclusion of multiple factors, such as research design and investigator demographics, enhances the study's scope and depth. The investigation of these factors enables a holistic understanding of the research landscape, aiding in identifying gaps and imbalances in domains, designs, and ethical considerations.

While the study comprehensively covers the nature and characteristics of the proposals, we were unable to assess the completion of ongoing research. Another limitation of our study is that we did not take into account the approval process. The study also relies on the accuracy and completeness of data available within the research proposals, which could introduce bias or affect the reliability of the results.

CONCLUSIONS

Our results show that among the submitted proposals, cross-sectional studies with a focus on health promotion predominated. However, there were fewer therapeutic studies and drug-related trials. The findings will contribute to resource allocation planning, highlight potential gaps, and drive improvements in the research review system. This research can assist policymakers in our institute and others in strengthening the research ecosystem and promoting robust and impactful research endeavors in Nepal.

CONFLICT OF INTERESTS

The authors declare that they have no competing interests.

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