

Trend and Patterns of Research Proposals Submitted for Ethical Review in Nepal Health Research Council

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ABSTRACT

Background: The characteristics of research proposals submitted to the Nepal Health Research Council reflect the trend of health-related researches being conducted in Nepal. The objective of the study was to analyze research proposals submitted for the ethical review in Nepal Health Research Council from 2017 to 2019.

Methods: A retrospective record review of research proposals received over three years from 2017 to 2019 were analyzed. A total of 2,305 research proposals was included in the study. The number of research studies per year, types of study design, priority area of research, and rejected proposal were the intended variables for the study.

Results: 91.45% (503), 92.19% (748), and 755 (80.1%) of received proposals were approved from Ethical Review Board in 2017, 2018 and 2019. The number of research proposals increased every year (550 in 2017, 812 in 2018, and 943 in 2019). Among the approved proposals non-communicable disease (n=150; 15.90%) in 2019} was the topmost prioritized area in all three years followed by reproductive health [93 (9.86%) in 2019] and communicable disease [67 (7.10%) in 2019] respectively. Quantitative research was more than two-third in all the years. Among the approved proposals, more than half were for an academic purpose [610 (64.69%)]. The reason for the rejection of the proposal was the conduction of research before ethical approval [2 (0.36%) in 2017, 2 (0.25%) in 2018, and none in 2019].

Conclusions: There was a rising trend of research proposals for ethical clearance being submitted to the Nepal Health Research Council. Research related to non-communicable disease followed by reproductive health was the commonest one.

Keywords: Ethical approval; ethical review board; research proposals; record review

INTRODUCTION

The Government of Nepal established the Nepal Health Research Council (NHRC) in 1991 to regulate research activities in Nepal.¹ As per the NHRC Act 1991, the institution has been entrusted with the responsibility to review all the health-related proposals proposed to be conducted in Nepal for scientific and ethical soundness of the research proposal.^{2,3}

NHRC receives 686 proposals every year on an average for the ethical review process.⁴ Government of Nepal and NHRC have updated Health Research Priority Areas of Nepal in 2019.⁵ It is essential to find out if the studies are being conducted in the priority areas set by the Government of Nepal to fulfill the gaps and make evidence-informed decisions in the health sector. However, the assessment of studies conducted in Nepal set on priorities areas is lacking. This study aimed to

assess the pattern and characteristics of the research proposals submitted to Ethical Review Board (ERB) for the ethical review from 2017 to 2019.

METHODS

A retrospective record review was conducted in Nepal Health Research Council with the study duration of six months in which all research proposals received between 2017 and 2019 were included for the study. The data of proposals were collected from the ethical review online system of NHRC after signing the confidentiality agreement form. All the authors after registering in the online system of NHRC submitted their portfolio along with details about the proposed study under various titles such as the background of the study, rationale, and objectives. The proposal submitted for ethical approval were assigned to subject experts for review, expert opinion, and the proposals were further processed to

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the ERB meeting for the final decision. All submissions for ERB were discussed at the weekly meetings. All submissions, exemptions, decisions, responses, amendments, extensions, resubmissions, and approvals were processed by the ERB secretariat staff.⁶

The privacy of the proposals was maintained. All the proposals submitted for the ethical review process to ERB were included in the study. The research proposals were considered as closed or inactive proposals if the investigator did not respond to the reviewer's comments within three months as per the standard operating procedures for Ethical Review Board.⁷ Permission from the administrative section of Nepal Health Research Council was taken along with ethical clearance from the National Ethical Review Board for this study. Research areas included in the research proposals were on adolescent health, biomedical research, emergency, trauma, and clinical trial, health information technology, disability, drugs and vaccine trial, essential medical products, health workforce, human genetic, gender-based violence, health economic, health in altitude, universal health coverage, zoonotic, population and population dynamic, Ayurveda, urban health, dentistry and mountain medicine.

The collected data was entered in MS-Excel and then edited and checked. Data were analyzed using SPSS software version 16. Descriptive statistical analysis was carried out to find frequency and percentage for binary data.

RESULTS

In total, 550, 812, and 943 proposals were registered in 2017, 2018, and 2019 respectively. Out of which 503 (91.45%) proposals in 2017, 748 (92.19%) proposals in 2018, and 755 (80.1%) proposals in 2019 were approved through ERB respectively. The number of submitted proposals increased from 550 to 943 in the period of three years (Table 1).

Table 1. Fate of received proposals in ERB (n=2,305).

Status	2017	2018	2019
Approved	503 (91.45%)	748 (92.19%)	755(80.1%)
Rejected	2 (0.36%)	2 (0.25%)	0(0%)
Withdraw	4 (0.73%)	15 (1.85%)	16(1.7%)
On process	0 (0%)	0 (0%)	84(8.9%)
Closed proposal	41 (7.45%)	45(5.54%)	88(9.33%)
Total	550	812	943

Similarly, two proposals were rejected in 2017 and 2018 while none of the proposals was rejected in 2019. The reason for the rejection of these proposals was the completion of research procedures before obtaining ethical approval from the ERB of NHRC (Figure 1).

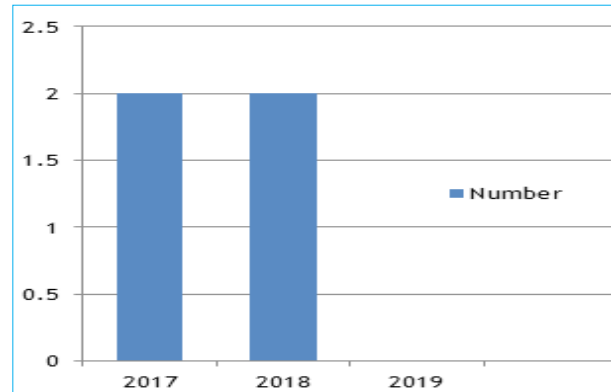


Figure 1. Reasons for Rejection of Research Proposals (n=2305).

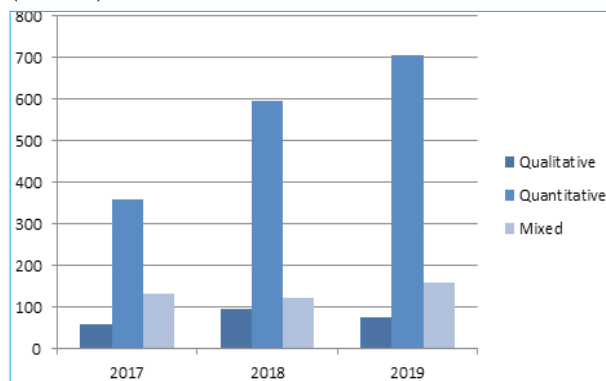
The number of proposals withdrawn by the researcher was 4 (0.73%), 15 (1.85%), and 16 (1.7%) respectively reflecting the significant rise in proposal withdrawal in the last two years. In a similar line, 41(7.45%), 45 (5.54%), and 88(9.33%) proposals were closed in 2017, 2018, and 2019 respectively based on the criteria mentioned in Standard Operating Procedure of National Ethical Guidelines for Health Research.

Non-communicable disease (NCD) was the most favored area by the researchers; in all three years which covered the highest percentage of proposals submitted to ERB. NCDs accounted for 75 (13.64%) in 2017 and 104 (12.81%) in 2018 and 150 (15.90%) of overall submitted proposals. Miscellaneous 170 (30.90%), Communicable disease 54 (9.82%), Mental health 41(7.45%), and Health Care Delivery 39 (7.09%) were subsequently most prioritized areas in which proposals were submitted in 2017. Similarly, miscellaneous 275 (33.86%), Sexual and Reproductive health 79(9.73%), Communicable disease 77(9.48%), and Neonatal and child health 65 (8.01%) were the most prioritized areas favored by researchers in 2018. Miscellaneous 310 (32.87%), Sexual and Reproductive health 93 (9.86%), Mental health 71(7.53%), and Communicable disease 67(7.10%) were the most prioritized areas favored by researchers in 2019 (Table 2).

Table 2. Total number of proposals according to priority area (n=2305).

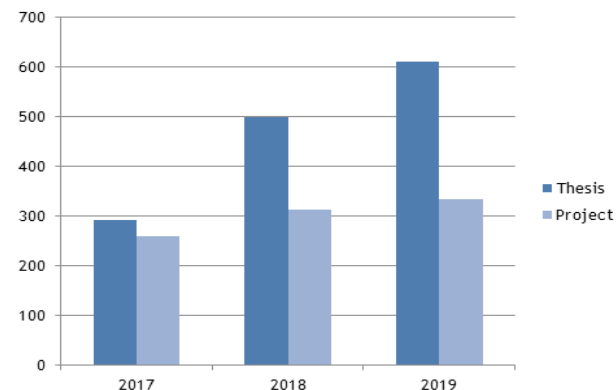
S.N	Priority Area	2017	2018	2019
1	Non-Communicable disease	75 (13.64%)	104 (12.81%)	150 (15.90%)
2	Sexual and Reproductive Health	49 (8.91%)	79 (9.73%)	93 (9.86%)
3	Communicable disease	54 (9.82%)	77 (9.48%)	67 (7.10%)
4	Neonatal and Child Health	36 (6.55%)	65 (8.01%)	50 (5.30%)
5	Mental Health and Substance abuse	41 (7.45%)	48 (5.91%)	71 (7.53%)
6	Maternal Health	25 (4.55%)	45 (5.54%)	58 (6.15%)
7	Health Care Delivery	39 (7.09%)	39 (4.80%)	46 (4.88%)
8	Nutrition, Food and Safety	23 (4.18%)	31 (3.82%)	55 (5.83%)
9	Environment and occupational	29 (5.27%)	27 (3.33%)	25 (2.65%)
10	Geriatric	9 (1.63%)	22 (2.71%)	18 (1.91%)
11	Drug and Vaccine Trial	8 (1.45%)	5 (0.62%)	17 (1.8%)
12	Miscellaneous	170 (30.90%)	275 (33.86%)	310 (32.87%)

Moreover, the trend of conducting quantitative research increased from 360 (65.45%) in 2017 to 595 (73.28%) in 2018 and 706 (74.87%) in 2019 (Figure 2). Similarly, the study on drug and vaccine trials was also on the rise (Table 2).

**Figure 2. Proposals according to the study type.**

Similarly, most of the research approvals were for partial fulfillment of the thesis which was 291 (52.91%) in 2017 that increased to 500 (61.58%) in 2018 and 610 (64.69%)

in 2019 (Figure 3).

**Figure 3. Proposals submitted according to their type.**

DISCUSSION

The study findings depicted an increasing trend of research in the miscellaneous area emphasizing the need for exploring further details in this area. On the contrary, there was a decreasing trend of proposal submission in the area of communicable disease in the subsequent last two years. This area was the second most prioritized area in 2017 that gradually fell to fourth and fifth place in 2018 and 2019. The burden of disease in Nepal is changing from communicable diseases to non-communicable diseases which might have led the researchers bring change in their priority areas and thus leading to decreasing trend of proposals related to communicable diseases.⁸ Mental health-based research was in increasing trend in the subsequent three years similar to findings from a systematic analysis of China and India.⁹ This could be attributed to the increasing prevalence of mental illness in the world. Around 450 million people are currently affected by mental disorders placing it as the leading cause of ill-health and disability worldwide.¹⁰ In Nepal, about 13% of adult and 11% of children are suffering from mental health disorders. This could have influenced researchers towards this kind of study.¹¹ Sexual and Reproductive health was the third most common area prioritized by the researchers for research conduction in both 2018 and 2019. Sexual health means more on reproductive health. This is a priority area in global health and a lot of efforts have been made in the last decade to reduce the maternal mortality and use of contraception which might be the reason that lots of research are being done in this area.

The highest number of approved proposals belonged to the academic thesis as it covered more than 50% in three years. The trend of thesis submission for the ethical review process was increasing as it increased by

almost 8% in 2018 and 3% in 2019 than the respective previous years. There are various reasons for more academic research proposals. Nepalese Universities have made obligatory to have a certain number of articles to be published for academic promotion. With an increasing number of medical colleges and faculty in Nepal, this trend can be easily understood.¹² Nepal Medical Council has made regulatory guidelines for post-graduate students and trainees to submit the thesis compulsorily to pass the exam.¹³ In similar line, Nepal Health Research Council has formed several Institutional Review Committees in academic and medical institutions to promote ethical conduct of research and facilitate academic research. However, there are many academic institutions in Nepal that does not have Ethics committee due to various reasons. This might be the main reason for increased number of academic proposals submission to NHRC.¹⁴

In our study, the number of proposals withdrawn was found to be increasing with each year, the reason for which is not particularly clear as the researcher can withdraw the proposal at any time without mentioning any reasons.⁷ The reasons behind the withdrawal of proposals could be attributed to various factors relating to the author, technical issue, and documentation. The prime reason for conduction of research and application of ethical clearance depicts the severe lack of awareness in the part of the researcher and understanding of policy implementation of ethical requirement as mandatory for proper conduction of research.

The study only analyzed the trend of research in Nepal in the last three years but did not highlight the quality of the proposal submitted in areas of proper methodology, adherence to ethical values. Health research plays a vital role in improving health outcome and equity in the country and reach the health needs of community. The researchers need to recognize the priority area and conduct research. However, the research conducted in LMICs are mostly Donor driven and lacks priority setting and Nepal is no exception.¹⁵

CONCLUSIONS

Overall, an up growing trend of research proposals being submitted for ethical approval was seen in the last three years. Among those proposals, non-communicable diseases followed by sexual and reproductive health were the most prioritized. Similarly, the proposals on mental health and maternal health were also increasing.

ACKNOWLEDGEMENTS

We would like to acknowledge Mr. Subash Ghising for his support in the data collection and compilation process of the study.

CONFLICT OF INTEREST

None

REFERENCES

1. Nepal Health Research Council [Internet]. About. Government of Nepal. [cited on June 9, 2020]. Available at: <http://nhrc.gov.np/about/>
2. Nepal Health Research Council. Nepal Health Research Council Act, 2047 (1991). Kathmandu: Nepal Health Research Council; 1991. [PDF]
3. Nepal Health Research Council. National Ethical Guidelines For Health Research in Nepal and Standard Operating Procedures. Ramshah Path, Kathmandu: Nepal Health Research council; 2011. [PDF]
4. Nepal Health Research Council. Health Research System in Nepal. Nepal Health Research Council. 2006. p. 1–20. [PDF]
5. Nepal Health Research Council. Health Research Areas of Nepal 2019. Health Research Areas of Nepal 2019 Kathmandu; 2019. [PDF]
6. Nepal Health Research Council. National Ethical Guidelines For Health Research in Nepal. Ramshah Path, Kathmandu: Nepal Health Research council; 2019. [PDF]
7. Nepal Health Research Council. Standard Operating Procedures (SOP) for Ethical Review Board. 2019. [PDF]
8. Nepal Health Research Council (NHRC), Ministry of Health and Population (MoHP) and Monitoring Evaluation and Operational Research (MEOR). Nepal Burden of Disease 2017: A Country Report based on the Global Burden of Disease 2017 Study. Kathmandu, Nepal: NHRC, MoHP, and MEOR; 2019. [PDF]
9. Charlson FJ, Baxter AJ, Cheng HG, Shidhaye R, Whiteford HA. The burden of mental, neurological, and substance use disorders in China and India: a systematic analysis of community representative epidemiological studies. *Lancet*. 2016;388(10042):376–89. [PubMed]
10. World Health organization. The World Health Report 2001: Menatal Disorders affect one in four people. Cited on June 12 2020. Available at: <https://www.who.int/news/item/28-09-2001-the-world-health-report-2001-mental-disorders-affect-one-in-four-people>
11. Jha AK, Ojha SP, Dahal S, Sharma P, Pant SB, Labh S, et al. Prevalence of mental disorders in Nepal: findings from the pilot study. *J Nepal Health Res Council*. 2019 Aug

- 4;17(2):141-147. [[PubMed](#)] [[JNHRC](#)]
12. Magar A. Scientific publications in Nepal. J Nepal Health Res Counc. 2012 Sep;10(22):243-9. [[JNHRC](#)]
13. Nepal Medical Council. Regulations for postgraduate medical education (MD/MS programs). Nepal Medical Council. 2017. Cited on June 12 2020. [[PDF](#)]
14. Nepal Health Research Council. Guidelines for Institutional Review Committees (IRCs) for Health Research in Nepal. Kathmandu: NHRC; 2016. 48p. [[PDF](#)]
15. McGregor S, Henderson KJ, Kaldor JM. How are health research priorities set in low and middle income countries? a systematic review of published reports. PLoS One. 2014;9(10):e108787. [[PubMed](#)]