

Research during COVID-19 Pandemic: Perspectives from the Ethics Committees of a Lower Middle Income Country

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ABSTRACT

The pandemic of Coronavirus Disease 2019 (COVID-19) has created paradoxically a good opportunity globally to conduct research in the field of health and social science, and a Lower Middle-Income Country (LMIC) like Nepal is not an exception in this regard. During this ongoing pandemic, the Ethical Review Board (ERB) of Nepal Health Research Council (NHRC) has received numerous research proposals regarding COVID-19. As its main responsibility is to ensure participants' safety, at the same time maintaining the scientific standard of research, the ERB has meticulously gone through all the proposals received so far. During this situation of a health emergency, the ERB of NHRC has had a different experience compared to the usual time. Its strength, weakness, opportunities, and threats have been like never before.

KEY WORDS

Coronavirus disease 2019, Ethical review board, Ethics, Research

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INTRODUCTION

Time and again the world has been facing deadly epidemics and pandemics, be it severe acute respiratory syndrome (SARS) coronavirus outbreak of 2002-2003, pandemic of influenza A (H1N1) of 2005, Middle East respiratory syndrome (MERS) coronavirus of 2012, West Africa Ebola virus disease of 2014, Zika virus of 2015, or the current COVID-19 pandemic.¹⁻⁶ Research in such critical times is very important, as it not only helps to assess the current scenario but also to develop new treatments, strategies, and methods to cope with these deadly diseases.⁷ The World Health Organization (WHO) has provided guidelines about research ethics during health emergencies which emphasize that the importance of ethics in research during emergencies cannot be undermined. The guidelines have equally highlighted the importance of research during an outbreak and on the aspect that whatever the situation, the ethical issues including the informed consent of any research should not be compromised at any cost. Every research during health emergency especially the trials should not be conducted without the scientific validity and acceptability of methodology to the community of participants.⁷

Research ethics during any health emergency: Global Scenario

The American Medical Association Code of Medical Ethics has stated core standards for research that involves human participants during public health crises. It has provided different codes of ethics such as- physician involvement in research, informed consent in research, study design and sampling as well as principles for disseminating research results among others.⁸

The role of the Ethical Review Board (ERB) is vital especially in the situation of a health emergency as its responsibility is highly increased because large numbers of new research proposals have to be reviewed in a short period of time. Also, the ERB has to meticulously go through the proposed researches to make sure the scientific standard is maintained and no research harms the public or violates their rights but contributes to science to make a better understanding of disease to improve public health during health emergencies.^{9,10}

A workshop was done in March 2018 by the World Health Organization Global Health Ethics Team and the African coalition for Epidemic Research, Response, and Training with the participation of 29 countries regarding ethics preparedness during an outbreak. It suggested that there is a need for the Ethics Committee to develop a formal national Standard Operating Procedure (SOP) for emergency response ethical review along with the procedures for multinational emergency ethical consultation. It further recommended that researchers should, at least, submit preliminary data sharing and sample sharing plans that reflect the benefit to the population from which participants are drawn.¹¹

Considering ethical issues is undoubtedly important but is equally challenging while conducting research during health emergencies due to limited time and resources, instability, and increased health and social needs in an atypical situation.¹² It is more arduous in a lower-income setting where resources are always scarce. A study done by Schopper et al showed that the ERB may face challenges while reviewing research proposals which are resolved by discussion at ERB meetings and by consultation with experts.¹³

Research ethics during health emergency (particularly COVID-19): Scenario of a Lower Income Country, Nepal

Nepal Health Research Council (NHRC) is the apical body that is responsible for promoting and regulating health-related researches in the country. Ethical Review Board (ERB) at NHRC along with 52 accredited Institutional Review Committees (IRCs) located at various health institutions all over the country, ensure the maintenance of ethical principles in health research. During the time of the health emergency, their responsibilities are even higher. As a regular process, the ERB, NHRC follows a structured process to review the proposals. After receiving a research proposal through the online portal of ERB, NHRC, there is an initial screening done by secretariat staff followed by reviews of the pundits in respective fields of study. If there are any improvements to be made then comments are sent to the researcher and are encouraged to address soon. The proposal is then forwarded to the meeting of ERB where a decision is made to either approve, approve with minor revision, resubmission if required major revision or decline based on the technical, ethical and scientific quality of the proposal. Apart from other studies, ERB received more than 250 (from January 2020 to October 2020) proposals of COVID-19 related studies exclusively. These studies were reviewed on a fast-track basis without compromising the quality of the study. The ERB of NHRC had a unique experience in doing so which is explained in figure 1.

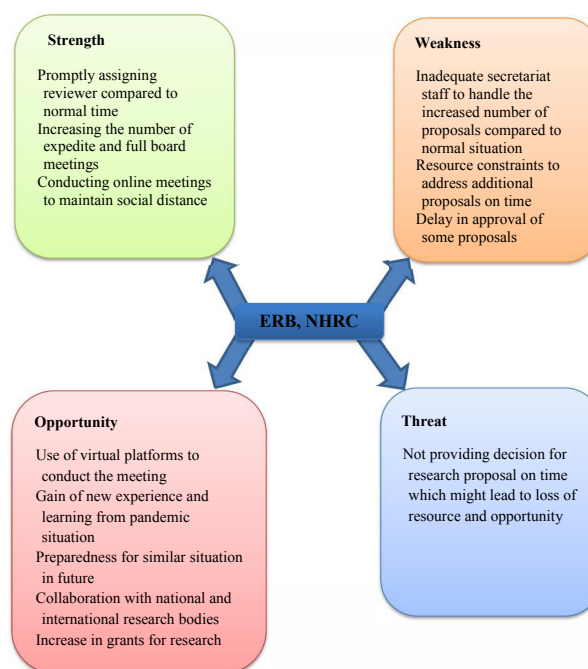
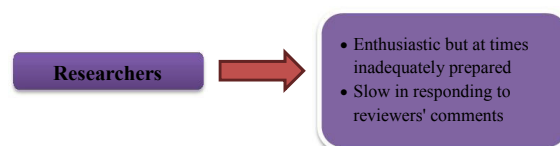


Figure 1. SWOT analysis of ERB, NHRC at the time of COVID-19 health emergency

In the eyes of ERB, most of the researchers were enthusiastic but at times inadequately prepared and slow in responding to the comments made by the reviewers.



Reasons for the delay in providing approval on time

Considering the situation of the pandemic, the ERB, NHRC accelerated the review process to its maximum capacity. However, the quality and essential elements of the research were not undermined in any way. Only in a few instances, the researcher had to wait for some time before proceeding with a review. There were few common issues faced in most of the proposals and for the sake of correction and clarification, those were returned to the researchers. Some researchers were prompt in responding while others were well behind time. This was the most common reason for the delay in making decisions regarding the proposal. Table 1 shows the common technical and ethical issues encountered during the proposal review and table 2 highlights some issues related to the reviewers.

Table 1. Common technical and ethical issues encountered in the proposals

Lack of clarity in the title
Unclear methodology
Unjustifiable sampling technique including inclusion and exclusion criteria
No plan for data analysis
No plan for dissemination of results
Lack of complete informed consent document
Ethical component not included properly
Failure for timely submission of required documents
Absence of national principal investigator (only foreign PI)
Unjustifiable budget
Unjustifiable timeline of study
Problems in registry (in case of clinical trials)
Delay to pay the processing fee

Conclusion and Way Forward

The current emergency health situation is a novel experience for many of us. Experience can be a good teacher for all, the ethics committee, researchers and reviewers. The ERB, NHRC also has had a rich experience in this pandemic especially in the later months. It has been realized that researchers as well as reviewers both need to be prepared to face this type of situation at any time. The researchers should never be in a rush to conduct research that they forget to include essential components especially in the time of health emergencies where research participants

Table 2. Some issues related with reviewers

Limited number of experts reviewers
New experience of Pandemic for most of the reviewers
Pressure to review a large number of proposals within limited time
Couldn't give enough time to non-COVID-19 related proposals

and general people are in a vulnerable state. As most of the research was conducted through virtual platforms, standard tools must be followed to ensure technical and ethical quality of the research. Similarly, the NHRC should increase its resources and capacities considering the increasing volume of the proposals. Arrangements should be made to address non-COVID-19 related research as well because they are equally important in the long run. Reviewers must be pre-oriented to face the possible situation in a health emergency. Standard research ethics should be maintained under any circumstances to safeguard research ethics standards, scientific merit, and right and wellbeing of the research participants. Albert Einstein once said, "Relativity applies to physics, not ethics."

It would be of interest to the community of researchers, academia, and stakeholders in health services that a review of the research proposal received and its scope be conducted to guide the researchers. Such information will help guide future research in uncharted areas and to pursue more in-depth studies in certain areas where previous research has identified further unanswered questions.

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