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Article abstract

This case study outlines an ethics approval process experienced during a maternal health research project in Nepal. The Government of Nepal established the Nepal Health Research Council (NHRC) in 1991, along with the Scientific and Ethics Committee reviewing health related research. However, not all researchers apply for ethics approval. Although researchers may claim a lack of clarity on the kinds of research studies needing approval, the authors argue that the guidelines are sufficiently clear if explored and duly followed. The inconsistencies in seeking ethics approval from NHRC could simply mean that researchers are not aware of this ethical review process. Perhaps the guidelines are not strictly enforced. Nevertheless, as researchers it is our responsibility to seek ethical approval as a matter of principle, without considering it a barrier to research.



ÉTUDE DE CAS / CASE STUDY

Nepal Health Research Council Paves Path to Ethical Research Processes

Sunisha Neupane¹, Chaitali Sinha²**Résumé**

Cette étude de cas décrit un processus d'approbation éthique lors d'un projet de recherche sur la santé maternelle au Népal. Le gouvernement du Népal a créé le Conseil de recherches en santé du Népal (NHRC) en 1991, ainsi que le Comité scientifique et d'éthique qui examine la recherche sur la santé. Cependant, tous les chercheurs ne demandent pas d'approbation éthique. Bien que les chercheurs prétendent un manque de clarté sur les types d'études nécessitant une approbation, les auteurs soutiennent que les lignes directrices sont suffisamment claires si elles sont explorées et suivies. Les incohérences dans la recherche de l'approbation éthique de la NHRC pourraient simplement signifier que les chercheurs ne sont pas conscients du processus d'examen éthique. Peut-être que les directives ne sont pas strictement appliquées. Néanmoins, en tant que chercheurs, il nous appartient de demander l'approbation éthique par principe, sans considérer celle-ci comme un obstacle à la recherche.

Mots clés

recherche sur le développement, évaluation éthique de la recherche, recherche en santé, Népal

Abstract

This case study outlines an ethics approval process experienced during a maternal health research project in Nepal. The Government of Nepal established the Nepal Health Research Council (NHRC) in 1991, along with the Scientific and Ethics Committee reviewing health related research. However, not all researchers apply for ethics approval. Although researchers may claim a lack of clarity on the kinds of research studies needing approval, the authors argue that the guidelines are sufficiently clear if explored and duly followed. The inconsistencies in seeking ethics approval from NHRC could simply mean that researchers are not aware of this ethical review process. Perhaps the guidelines are not strictly enforced. Nevertheless, as researchers it is our responsibility to seek ethical approval as a matter of principle, without considering it a barrier to research.

Keywords

development research, research ethics review, health research, Nepal

Introduction

Public health and health systems research has gained a tremendous interest in low and middle-income countries. The Canadian *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2), Article 8.3 states that: "any research involving humans shall obtain necessary approvals from both the research ethics board (REB) at the Canadian institution under the auspices of which the research is being conducted and the REB at the research site" [1]. However, much work is required to ensure that the ethical dimensions are examined, and that the ethical processes and responsibilities are undertaken, when conducting research and when sharing research results in low and middle-income countries [2,3]. An ethical review of a health research study in a host country considers the national and cultural context, and adds valuable perspectives from host researchers and ethicists [3]. A national REB can ensure that a research project benefits the host country and the communities where the research is to be conducted. Unfortunately, results from research studies conducted by researchers from foreign institutions are not always shared with the participants, and the requirement for this is still a grey area [4,5]. Sharing results with participants fall under principle of respect for persons [4,5] and a national ethics approval process can potentially clarify such a requirement and suggest in-country knowledge translation approaches. A national REB could further contribute towards tracking studies and gathering results across different research projects conducted in the country. It is, therefore, crucial that host countries are able to develop robust ethics approval processes to provide guidance to researchers, protect local communities, and track the range of different research studies being conducted over time. It is equally important that researchers actively seek and meaningfully engage in the process of acquiring a national ethics approval where they wish to conduct the research. Yet, studies are still being conducted without formal ethics approval from the host countries [3]. Teijlingen and Simkhada provide reasons to explain why researchers fail to apply for an ethics approval for health research in low and middle-income countries and demonstrate that there are assumptions made by the researchers [6]. This case presents an experience in acquiring ethics approval from Nepal Health Research Council (NHRC) for health-related research; it demonstrates that, even with extenuating local circumstances, the process need not be considered a "barrier" to research [3].

Case Presentation

This case study describes an experience in obtaining ethics approval from a national REB for maternal health research in Nepal. The aim of the research was to understand the maternal health situation and needs of women in rural areas of Baglung. To understand the maternal health needs, participatory research was conducted with data collection tools such as interviews, focus group discussions, and participatory workshops. Ethics approval for the research project was obtained from both the Health REB of the Université de Montreal (CÉRES) and the NHRC.

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The Nepal Health Research Council (NHRC)

In 1991, the Government of Nepal established the NHRC. The Scientific and Ethics Committee within the NHRC used to review and approve health research in Nepal [7]. The first National Guidelines for Ethical Review were published in 1995, and the Scientific and Ethics Committee was formalized as an Ethical Review Board (ERB) in 2001. More than a decade after the forming of the ERB, it is still the case that not all health researchers apply for ethics approval or register their health research with the NHRC [6,7]. Thus, it has become impossible for the NHRC to be informed of and track the quantity or type of health studies that are conducted in Nepal [7,8]. One can surmise that a lack of complete adherence in seeking ethics approval from NHRC is, in part, due to assumptions made on the part of researchers, as well as on the part of NHRC staff. For example, Sharma and colleagues mention that NHRC guidelines do not provide a clear definition of health research [7]. This can create an assumption, by researchers, of the types of research that are required to go through the NHRC ethical review process. Having read the NHRC document titled *National Ethical Guidelines For Health Research in Nepal and Standard Operating Procedures, January 2011* (pg. 3-4), we argue that the types of research considered “health-related”, and thus requiring an approval, can be inferred from the document. Although the types of research needing ethics approval are not explicit on the NHRC [website](#), the guidelines nonetheless state that any research involving human participants necessitates ethics approval before conducting research in Nepal [9]. Moreover, the NHRC can clarify further if contacted by the researcher.

Ethics approval process: an experience

In our particular case, the lead researcher is fluent in Nepali. All email communication was in English, whereas conversations over the phone and in-person took place in Nepali.

The process was hassle-free and easy to follow. There is a ‘Research Proposal Approval Format’ – a form that researchers are able to download from the NHRC website. In addition, there is a [checklist](#) of documents required for the application (e.g., cover letter, project protocol, photo of the principal investigator (PI), résumé, consent form and data collection tools in Nepali, an approval letter from the University, and a fee of US\$100 for research with a budget less than US\$10,000). If the PI is a foreign national, he/she must collaborate with a Nepali researcher as a co-investigator, and they must file an application together (the application also requires the résumé and passport details of the Co-PI). When asked about this requirement, the NHRC officer mentioned that this measure is included as a way to prevent data exploitation practices.

Timeline

The lead researcher called and emailed the NHRC officer with queries before the application was submitted (Table 1).

Table 1. Questions and answers with NHRC staff during the process

| Question | Response |
|--|---|
| 1. I am a student; do I need to submit a full application? What if I already have an ethics approval from my University? Note: the question arose because there is a section called “for students”. | Yes, as a student you submit the full application with the additional documents required for a student (same day response). Yes, you submit the full application even if you have an approval from your University. |
| 2. Is it okay to submit the application in parts if that makes the process faster? Note: Was waiting for ethics approval certificate from the University | Yes, (same day response) |
| 3. Do we need parent’s assent form for participants less than 18 years of age? | Yes (same day response) |

We were told that the approval process would take 2-4 weeks after the application submission. The application was submitted April 21, 2015, a few days before the 7.8 Richter scale earthquake that hit the country. The earthquake caused substantive damage to infrastructure and resulted in many immediate casualties, as well as longer-term displacement and trauma. Not surprisingly, priorities within the NHRC shifted as a response to this shock. Although the NHRC officers were back to work within a week, their attention was on studies needing urgent consideration. Thus, the review process took longer than anticipated. The lead researcher was provided with comments 10 weeks after submission of the application and received an approval a week after re-submission with the amendments. Overall, approval was received within 11 weeks. We believe that this was an enormous achievement, in light of the nature and scope of the recent natural disaster in the country, and the spike in new studies that were submitted which were time sensitive. From the experience, we believe that the time required to receive an approval depends on the i) completeness of the application (i.e., carefully following the checklist), ii) quality of the research proposal and related protocol, and iii) the timeliness of approaching the local ethics board to allow for sufficient lead time before

initiating data collection. In this case, the NHRC officers were helpful and answered all the questions that we had in a timely and thorough manner.

Conclusions

Although the process of preparing an application can be tedious, ethical review is a crucial step in health research. This case study demonstrates that it can be a straightforward process if the researcher limits her assumptions about the process, and engages with the local REB early on. Although one can argue that the guidelines from local REBs are not always crystal clear or strictly enforced, as researchers, it is our responsibility to seek ethics approval from the host country before we embark upon a health research project.

Based on the experience, we have a concrete suggestion for the NHRC (as the local REB) and researchers to facilitate an effective process of seeking ethics approval for health-related research:

- For the NHRC: in addition to the list of required documents, we suggest providing i) a clear definition of health research, ii) examples of the kinds of research that require an ethics approval, and a sense of iii) how long the review process takes. If published on the NHRC website, these pieces of information could help prevent false assumptions and increase the application rate.
- Researchers: ensure all the required documents are complete, of high quality, and submitted in a timely manner. Researchers can email the NHRC officers (in English) to ask any questions they may have to avoid confusion.

Questions to consider

1. Is there enough ethics training available to Canadian researchers who are conducting research in international contexts?
2. Should there be a more specific and clear definitions of 'health related' research? For example: what about studies that look at water and sanitation and do not directly involve human participants?
3. Should normal procedures for national ethics review be followed after a disaster, such as the Nepal Earthquake 2015? Do disasters represent an exception to the general rule of requiring an ethical approval?
4. Would it ever be legitimate to initiate research without national approvals? For example, circumstances such as long delays in ethics approval, deadlines with research funding.

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Conflit d'intérêts

Aucun déclaré

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Conflicts of Interest

None to declare

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