

Ethical approval in developing countries is not optional

Edwin van Teijlingen
School of Health & Social Care, Bournemouth University

&
Padam Simkhada
ScHARR, University of Sheffield

Abstract

When conducting health and medical research it is not only important to do the research ethically, but also to apply for prior ethical approval from the relevant authorities. The latter requirement is true for developed countries as well as developing countries. We argue that simply applying for research ethics approval from an institutional review board at a university based in a developed country is not enough to start a health research project in a developing country. The paper also suggests a number of reasons why researchers may fail to seek local research ethics permission in developing countries. We use a recent paper reporting research conducted in Nepal and published in an international journal as a case study to highlight the importance of being sensitive to local requirements regarding applying for and registering health and medical research.

Introduction

There exist a growing literature on the practice, politics and ethics of research conducted in developing countries, [1-5], including publications focused on research ethics committees in developing countries. [6] Despite this in a recent paper in one of the leading international social science and medicine journal Smith and Neupane (the authors) offered just one sentence about research ethics, namely: "Syracuse University's Institutional Review Board exempted the study from review." [7] Nothing unusual for a health study in this kind of international journal. As part of their health policy study in Nepal Smith and Neupane interviewed representatives of government agencies, international agencies and donors, nongovernmental organizations, medical and research communities. They explained their selection criteria and added "We selected interviewees based upon their close involvement in or knowledge of newborn survival advocacy, policy decisions, research and program implementation in Nepal." [7]

We have two observations on the ethical approval for this research project. First, we wondered why the university's Institutional Review Board (IRB) exempted the study for the need of an ethical review. We assumed the IRB exempts interview-based health studies like this one from review just because the researchers do not interview (vulnerable) patients. We posed this question in an email to the IRB. The director of the Office of Research Integrity and Protections at Syracuse University replied by email (Feb. 2011) to reject our suggestion. She explained: "It is not correct that Syracuse University exempts interview health studies from review simply because the researchers do not interview patients. ... it was determined to be exempt from review under the federal regulations." The reasons for exemption, in accordance with these regulations, included (a) the fact that it was a survey of public behaviour where there was no risk of social damage to participants (the criterion for non-exemption being that "disclosure of human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation"); and (b) it was a study of human behaviour where "the human subjects are elected or appointed public officials or candidates for public office." The director finished her email with the comment: "I cannot give you any specifics of the determination or details of the research protocol without permission from the

investigators.” In short, the IRB exempted the study from ethical review because of the nature of the survey and the participants, and it is clear that the authors have followed due procedure with their IRB.

Our second observation is more important, namely that after the statement the IRB “exempted the study from review”, one would have expected the authors to state something along the lines of the following: “This research has been granted approval by the Nepal Health Research Council.”

Obviously, we passed on our concerns to the editors of the journal. In reply the managing editor emailed us (Feb. 2011) to say: “Thank you for your correspondence about the ethical approval process for this published paper in the journal. We give close attention to statements of ethical approval when reviewing papers. As you note, some IRBs/ethical committees do still exempt studies of this kind ... we ask authors to make sure that this is stated in their papers, as happened here. You note that approval should also have been sought from the Nepal Health Research Council; this is not something that we were aware could be the case as editors.”

We also appreciate that the journal *Social Science & Medicine* does not publish letters to the editors, but its web pages suggest that it accepts “Submitted or invited commentaries and responses debating, and published alongside, selected articles.” Therefore, we thought our observations might be published as a commentary to alert future authors to the importance of seeking ethical approval in country, especially in a developing country. However, *Social Science & Medicine* rejected our commentary on the matter, which led us to prepare this Brief Report for the *Journal of Medical Ethics*.

After contacting the IRB and the editors of the journal we also contacted the first author of the paper. She accepted the criticism regarding the failure to apply for ethical approval in Nepal. In her email (July 2011) she stated: “Unfortunately, I was not aware of the Nepal Health Research Council before or during the conduct of our research. I agree that it is odd and perhaps I should have more actively inquired whether there was a review board process in Nepal that we needed to pursue. In partial defence, we interviewed several health ministry officials and health researchers in Nepal for our study and none brought this issue to our attention. I regret the oversight and agree with you that the proper course of action would have been to seek the approval (or exemption) of both the Syracuse University and Nepal review boards.”

Not seeking ethical approval in developing countries

There are a number of possible reasons why researchers from developed countries may fail to apply for ethical approval in a developing country when they are conducting research there. These include (a) ignorance, as in the case of the first author of the Smith and Neupane paper; some may assume that a developing country does not have a system, or a working, system for ethical review; (b) perceptions of cost; some may think that applying for ethical approval in country is expensive and/or time consuming; (c) perceptions of certain research being exempt, e.g. believing that certain health research does not need ethical approval; perhaps because it does not involve patients or health institutions or because it is ‘only’ a student project; and (d) arrogance or paternalism; some may feel that ethical approval from an institution in a developed country is good enough, if not better.

Applying for ethical approval in Nepal

Ten years ago the Nepal Health Research Council (NHRC) published its ethical guidelines for health research in the country. [8] The NHRC was created by an Act of Parliament in 1991 to promote scientific study and high quality health research in Nepal. The published ethical guidelines discuss general principles of ethics, and includes, amongst others, checklists for (a) assessing informed consent; (b) scientific merit of research proposals; and (c) ethical questions. It also sets out eight steps for research which is sponsored and/or funded externally, which are reproduced in Box 1.

Box 1 Ethical requirements in Nepal for research with external sponsors.

|The following conditions have to be considered before external sponsors can
|undertake research among the Nepalese people:
|
|The research is preferably responsive to the health needs and priorities of
|Nepal as well" as being sensitive to the existing culture and social values.
|The research cannot be carried out reasonably well in the sponsors' country.
|The research protocol has the approval of an Ethical Review
|Board/Institutional Review Board of the country of the sponsor.
|The sponsor should -consider means in which the research capability of Nepal
|can be strengthened and other means of compensating the community.
|The research process should be transparent.
|External sponsors should apply insurance to research participants in health
|research that involves more than minimal risk.
|In case it is necessary to transfer biological samples abroad, a memorandum of
|understanding has to be signed by the sponsor and NHRC defining clearly the
|purpose for the transfer, the material that is being transferred, ownership of
|intellectual property rights, and. provisions for privacy protection.
|The proposal has to be approved by NHRC.

Box 1 clearly states that the NHRC expects that the researchers have gained permission to do the research from their own institution's ethics committee (called IRB at most universities in the USA) and that they seek approval from the NHRC. It is regrettable that the authors, one of whom is based in Nepal, did not make the last step. The experience of submitting at least a dozen ethical applications in Nepal is that the system is relatively easy to use. The application form is available on the web and applying is not expensive. The comments one receives are generally relevant and helpful and feedback seems to be offered faster than in the UK. Moreover, we have never failed (yet) to gain research ethical approval in Nepal for our maternity care public health studies.

Developing countries such a Nepal often do not have the information systems to create an inventory of on-going health research, which means it is harder to keep an eye on the quantity and quality of such research. It makes it also less likely that research findings are appropriate for the country's needs and that the findings are, or can be, integrated into national health policy. Often developing countries only have snap-shot overview of the total volume of health research when someone conducts a bibliography review of the published health research literature, e.g. recently in Nepal. [9] One of the additional reasons of applying for research ethics permission for the NHRC is that it adds that particular study to the register of health research in Nepal.

One wonders what the editors of *Social Science & Medicine* would have done if the boot had been on the other foot. What if an academic paper was submitted by an author based in Nepal who studied patients in, for example, the United Kingdom? If in the submission the author had stated that she had applied for ethical approval to her IRB at her university in Kathmandu to interview pregnant women who were smoking as they step out of an antenatal clinic in Sheffield or Bournemouth. Suppose the authors' statement read something like: "Kathmandu University's Institutional Review Board exempted the study from review", would the journal have considered this to be appropriate or sufficient?

Final thoughts

We do not want to imply that Smith and Neupane have conducted unethical or bad research; on the contrary, their research is both excellent and timely. [7] Moreover, it is the kind of health-policy research that a country with limited research capacity desperately needs. Our key point is that resource-

poor countries like Nepal will find it very hard to assess and control what health research is conducted within its borders (and when and where and how) if researchers from resource rich countries do not inform them adequately. And if leading international journals do not enforce this requirement, what incentive is there for the next generation of researchers to go jump through the extra hoop of applying for in-country ethical permission?

Of course, editors of international journals cannot be expected to be aware of ethical bodies in every country, but perhaps they should start from the assumption that there are appropriate research ethics committees in every country to whom research should apply. The editors should be convinced by the researchers that there was no appropriate local research ethics committee at the time of the study. In the mean time it stays the responsibility of individual researchers to establish whether or not there exist an ethics committee in the country where they are planning to conduct their fieldwork/study.

Acknowledgements

We like to thank the two anonymous reviewers and the Associate editor for their useful comments on our original submission.

References:

1. Mandiyanike D. The dilemma of conducting research back in your own country as a returning student- reflections of research fieldwork in Zimbabwe. *Area* 2009;41:64-71.
2. Lorenzo C, Garrafa V, Solbakk JH, Vidal S. Hidden risks associated with clinical trials in developing countries. *J Med Ethics* 2010; 36: 111-115.
3. Wendler D, Emanuel E J, Lie RK. (2004) The standard of care debate: can research in developing countries be both ethical and responsive to those countries' health needs? *Am J Publ Health* 2004; **94**: 923-928.
4. van Teijlingen E, Simkhada P, Ireland JCM. Lessons learnt from undertaking maternity-care research in developing countries. *Evidenced-based Midwifery* 2010;8: 12-16.
5. Bhutta ZA. Ethics in international health research: a perspective from the developing world. *Bull World Health Organ* 2002;80:114-120.
6. Nyika A, Kilama W, Chilengi R, Tangwa G, Tindana P, Ndebele P, Ikingura J. (2009).Composition, training needs and independence of ethics review committees across Africa: are the gate-keepers rising to the emerging challenges? *J Med Ethics* 2009;35: 189-193.
7. Smith SL, Neupane S. Factors in health initiative success: Learning from Nepal's newborn survival initiative. *Soc Sci Med* 2011;72:568-575.

8. Acharya GP, Gyawali K, Adhikari R et al. (Eds). National ethical guidelines for health research in Nepal, Kathmandu, Nepal: Nepal Health Research Council, 2001. http://www.nhrc.org.np/guidelines/nhrc_ethicalguidelines_2001.pdf

9. Simkhada P, Baral YR, van Teijlingen E. Health and Medical Research: A Bibliometric Review. *Asia Pac J Publ Health* 2010;22:492-500.