

## Failure to apply for ethical approval for health studies in low-income countries

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### Abstract:

On too many occasions researchers conduct public health and/or epidemiological studies in low-income countries without the appropriate in-country ethical approval. This article reflects on some of the underlying reasons for not applying for ethical approval. The piece concludes that we need to start by educating our (junior) researchers and research students about the importance of research ethics. We conclude with a number of recommendations for researchers, scientific journal editors and reviewers and ethical committees in high-income countries to bring the message home to researchers that ethical approval should be sought in low-income countries if and when required!

**Keyword:** Bioethics; Developing Countries; Publications; research training

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## Introduction

Ethical issues are recognised as a crucial element in health research[1]. Most will agree that research ethics is global, i.e. that the general principles of research ethics can and should be applied equally to, for example, a public health study conducted in Dhaka or an epidemiological one in Kathmandu as it would in New York or Edinburgh. Hence the four principles of research ethics in the health field as outlined in Box 1 are universally recognised[2].

### Box 1 The universal ethical principles

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| <ul style="list-style-type: none"><li>• Do no harm / non-maleficence</li><li>• Do good / beneficence</li><li>• Justice</li><li>• Respect for autonomy</li></ul> |
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The World Medical Association (2015) regularly updates the so-called Declaration of Helsinki 1964, which outlines the ‘Ethical Principles for Medical Research Involving Human Subjects’[2]. One of these ethical principles is that proposals for medical and health research should be reviewed by appropriate ethics committees on their merits (and risk to the population included in the study). “The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins,” in the words of the World Medical Association[2].

### Research ethical approval

In low-income countries the social, cultural and economic contexts in which research is conducted often differ from those in high-income countries. It follows then that public health researchers would apply for research ethics approval to the relevant local authority, if national legislation requires one to do so. This case study addresses the issue of researchers failing to seek research ethics approval in low-income countries such as Nepal[3]. The authors have a combined experience of over two decades of conducting health research in Nepal, and they have published over one hundred papers related to Nepal. As such we are very much aware of the need to apply for research ethical approval from the Nepal Health Research Council (NHRC). The NHRC has been operational for over ten years as the key statutory and autonomous body to oversee research ethics in Nepal[4].

However, we have recently come across papers reporting public health research conducted in Nepal where the authors appeared not to have sought appropriate ethical approval in the country[5-6]. In addition, as widely published researchers on Nepal we are also often asked to review papers submitted to

international journals; paper reporting studies conducted in a range of South-Asian countries including Nepal. Both of us have reviewed research papers for different journals in which the researchers had not gone through the appropriate national channel for ethical approval. This situation is not unique to Nepal as a recently published paper on health research in Indonesia only had ethical approval from an Australian university[7]. Interestingly, Indonesia has at least 26 health-research ethics committees, mostly linked to universities[8]. Whilst a paper published in the *Journal of Nepal Medical Association* on a mixed-methods study in Bangladesh does not mention ethical approval at all[9]. Some researchers from high-income countries do not mention research ethic approval when doing research in a low-income country. For example, one European anthropologist having done fieldwork in Morocco leaves the reader guessing as to whether she has applied at all for research ethics approval to the appropriate national authority[10].

There is growing academic literature on the ethics of doing research in low-income countries[11-13]. In their study of over 200 health studies in developing countries, Hyder and colleagues reported that one quarter of these studies did not undergo any ethics review neither by an Institutional Review Board (IRB) nor by the Ministry of Health[14]. Therefore, we asked ourselves the question: ‘Why do researchers fail to apply for public health/epidemiological research ethical approval in low-income countries like Nepal?’ We have identified at least five possible explanations for such omission: (1) thinking that research ethics approval is not needed for researchers from high-income countries; (2) not knowing the country has an ethics committee; (3) applying to the ‘wrong’ authority, especially to those in high-income countries; (4) having worries about resource constraints; and (5) assuming that there are exemptions for non-clinical Public Health research. Of course these five reasons overlap and interact with each other, indeed several might be at play at the same time.

Researchers, especially those with experience of Public Health in low-income countries where no research ethics committee exist, may assume that there is no ethics committee in Nepal either. Sometimes local Nepali researchers are not aware of the need to reply for ethical approval, which points in the direction of a gap in their training. We may see this as a combination of innocence and ignorance.

Secondly, there exists perhaps occasionally a false sense of superiority among researchers from high-income countries when working in less developed countries. Some researchers may feel that own ethical standards scrutiny from an institutional review board at a prestigious university in a high-

income country such as the USA is good enough, if not better, than one could expect in a low-income country. This arrogance or sense of superiority links to notions of paternalism or neo-colonialism thinking that low-income countries are perhaps slightly backward as they are less developed economically and socially.

Thirdly, researchers may mistakenly apply to the wrong ethical authority. This is perhaps another symptom of such arrogance among international researchers is assuming that applying for ethical approval in own high-income country is enough and that no further ethical approval is required in Nepal. For example, a Canadian academic who has applied to the IRB of a university in the USA for research ethical approval for a Public Health project in Nepal may think not consider that one also needs host country approval. Or such academic may consider that the scrutiny from their prestigious university's IRB in, for example, the USA is good enough, if not better, than one could expect in a developing country with a moderate to high level of corruption. Hyder *et al.* suggested that some health studies may not have been reviewed in the developing country as it was assumed that the review had occurred at the collaborating institution in the West [14].

Applying to the wrong authority can also happen inside a low-income country. For example, Silwal and colleagues recently reported on an educational study around abortion in Nepal[15]. They had sought written permission to conduct the study from the VDCs and they obtained informed consent from each participant prior to interview, so they had thought about ethics and ethical approval, but they seemed to have failed to apply to NHRC.

Fourthly, some public health researchers may worry about cost or they may think that applying for ethical approval in a low-income country is bureaucratic and time consuming. Nepal scores high on the international corruption index so perhaps assumptions that a formal application may involves a load of hassle and perhaps paying bribes are not completely unfounded. It is worth remembering that Nepal ranked a lowly 126<sup>th</sup> out of 174 countries, according to the most recent Transparency International's Corruption Perception Index[16]. However, regarding the research ethics process, we can assure readers from our own experience that applying for research ethics approval in Nepal is relatively cheap, all above board and generally hassle free.

Finally, some researchers may have perceptions of certain population-based research being exempt from research ethics approval[14]. This mistaken perception makes sense as in some high-income countries in Europe researchers do not have to apply for research ethics permission for population-based

questionnaire-type epidemiology studies as these are generally seen as very low risk (in ethical terms). Thinking along the same lines, some believe that certain health research does not need ethical approval because it does not involve the study of individual patients or health institutions. Others mistakenly think that certain small epidemiological projects may not need ethical approval because they are 'only' a student project. The latter mistaken is not confined to researchers conducting Public Health research in low-income countries, it is also a common mistake in high-income countries.

### **Research in other low-income countries**

If there is no appropriate local research ethics committee health researchers should first consider seeking permission to conduct the research elsewhere, perhaps from the regional director of public health or a local representative of the ministry of health. We asked ourselves the question: 'When would we consider not applying for local ethical approval?' One answer could be: 'When it is clear that the local research ethics committee is corrupt and it always gives research approval if the applicants pay a bribe'. Another answer could be: 'When it is clear that the local research ethics committee is corrupt and it never gives approval if the study is likely to be critical of the local health care system, the director of Public Health and/or the government'. If research is for the greater good, for example a study into corruption in the local health care system, all researchers have a moral duty to conduct the research especially when local stakeholders do not want this research to take place. For example, if foreign researchers plan a Public Health study on inequalities in access to health care in Syria in 2015 they are unlikely to get ethical approval from the Syrian Government. One could argue that as long as the study is conducted ethically these researchers may be permitted to go ahead as their study is for the greater good of the oppressed Syrian people. Not only do these researchers have the moral duty to conduct the research they also have the duty to ensure that their research is conducted ethically. This is in itself an important point as in the end the responsibility for conducting a study ethically lies with the health researchers, not the authority that provides ethical approval[17-18].

### **Way forward**

Reflecting on the five explanations above, most fit into two overarching themes: (1) arrogance, and (2) ignorance. Arrogance related to thinking that research and research ethics in high-income countries are superior. As the former is often the case one can understand but not condone the notion that research ethics is also better. Secondly, ignorance about rules, regulation and procedures related to research ethics approval in both low-income and high-income countries. Furthermore,

we always need to remember that the final responsibility to ensure Public Health research is conducted ethically in low-income countries (but really everywhere) lies with the researcher. National policies, ethical review boards, guidelines all help point the researcher in the right direction, but in the end he or she is key responsible person that the research in the field (or the hospital, the school, prison, etc.) is conducted in an ethically sound way.

We offer some recommendations for the way forward. Academics, in both high-income and low-income countries, need to encourage junior researchers and postgraduate students to apply for research ethics approval in developing countries. The first step is to keep raising awareness about research ethics amongst (junior) researchers and our students. Secondly, we need to encourage editors of scientific journals across the globe to always insist on ethical approval being granted for manuscripts based on primary research. Thirdly, peer reviewers need to be check that ethical approval is granted by the appropriate body. For example, we would not expect the average medical or health journal editor to know about the regulations for research ethics across the globe, for example, in Nepal, Nigeria or Norway. But we do expect that some expert reviewers who review a paper on fieldwork conducted in Nepal actually know the ethical procedures in that country. Fourthly, IRBs in high-income countries should only be allowed to offer conditional ethical approval for fieldwork in low-income countries, with the main condition being that appropriate ethical approval should be sought locally too.

#### **Conflict of interest:**

The authors hereby declare that they have no financial or non-financial potential conflicts of interest.

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