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A case study of researchers' knowledge and opinions about the ethical review process for research in Botswana

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Abstract

Most countries, including Botswana, have established Institutional Review Boards (IRBs) to provide oversight of research involving human beings. Although much has been published on the structure and function of IRBs around the world, there is less literature that empirically describes the perspectives of stakeholders in low- and middle-income country (LMIC) settings regarding IRB processes. In this study, we employed primarily quantitative methods to examine the perceptions of researchers at the University of Botswana (UB) about the review of research protocols by local IRBs. Data were collected using a web-based survey (SurveyMonkey[1]). This was a preliminary effort to document some of the emerging

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experiences of researchers with ethics review in a context where both research and research oversight are relatively new. Findings from 85 researchers indicate that researchers recognized the need for an IRB to review all human research protocols, expressed the need for research ethics training, experienced high rates of approval at government ministries and UB, and generally believed that ethics review processes can help researchers themselves better understand and appreciate research ethics in general. Though only about one-quarter of respondents reported a more positive view of research ethics after interacting with the UB IRB, 56.5 percent reported no change. In contexts where IRBs have recently been established, it can be particularly important to document the perspectives of researchers in order to align expectations with capabilities, and identify areas where IRBs can improve operations. Future efforts to advance research ethics and ethical review in Botswana should include establishing research ethics training requirements and courses for researchers, increasing investment in IRBs and their training, further developing institutional and national research ethics policies, and formalizing agreements between IRBs and others involved in research oversight in the country to support coordinated review.

Keywords
Botswana, ethical review, institutional review board, knowledge, opinions, research ethics committee

Introduction

A number of international guidelines including the Nuremberg Code (1949), the Declaration of Helsinki (World Medical Association, 2013), the Belmont Report (Belmont, 1979), and the Council for International Organizations of Medical Sciences Guidelines (CIOMS, 2002) were formulated in an attempt to guide research involving human participants. These guidelines have served as the basis for numerous policies and regulations governing research and research ethics. Along with the requirement of informed consent, one of the most internationally recognized mechanisms for the protection of human subjects is the requirement of independent review, usually conducted by a research ethics committee (REC) or institutional review board (IRB). In its ideal form, the review process supports unbiased evaluation of the ethical aspects of a proposed research study. Although researchers and others ought not interfere with the decision-making processes of RECs, constructive open dialogue between researchers and RECs can be important to the quality and efficiency of ethical review (Eissenberg et al., 2006).

Much has been published on the goals and elements of IRB review, particularly within high-income country contexts; however, less literature empirically evaluates the perspectives of REC stakeholders in low- and middle-income country (LMIC) settings. Principal stakeholders in this context include researchers, research participants, and members of the wider public.

This case study presents the experiences of researchers in Botswana with two local ethical review processes – their perceived function and value. We employed primarily quantitative methods to examine the perceptions of researchers at the University of Botswana (UB) about the review of research protocols by local (institutional and national) research ethics committees. The findings contribute to literature on researcher–committee relations, and are of particular relevance to recently established committees seeking to become a part of their institutional research fabric.

Background

Although biomedical research involving human subjects has been conducted in Africa for more than half a century, most ethics committees on the continent were created in the 2000s (Rwabihama et al., 2010). Many committees were initially established with the primary objective of reviewing international research in which both the sponsoring and hosting countries were required to review the research protocol before commencement of the research project (Rwabihama et al., 2010). Furthermore, many IRBs in Africa now have Federal Wide Assurances (FWAs), a contractual assurance with the US federal government, and an indication that institutions have likely received US research funds or have collaborated with US-funded researchers. Whereas a number of IRBs were established as an element of international collaboration, some were established because of a locally recognized need for independent review (Kass et al., 2007). Today, most institution-based IRBs in Africa review a combination of projects that are internal and external to the institution (Kass et al., 2007).

Existing empirical literature describing IRBs in LMICs has focused primarily on structural and functional assessment, and, to a lesser degree, the perceived influence or impact of review. A case report including 12 IRBs from nine African countries indicated that the composition of IRBs involved in the study ranged from nine to 31 members (Kass et al., 2007). Many of the IRBs were reported to include members from various professional backgrounds, though one included only physicians and scientists and two did not have lay or non-scientist members. Another survey of 31 IRBs across sub-Saharan Africa found that members of 10 committees were all affiliated with the institution where the committees were based, raising concerns about the independence and objectivity of the reviews conducted by such committees (Nyika et al., 2009a). A needs assessment of IRBs in Africa found that nine of the 31 responding committees did not have standard operating procedures (SOPs) and seven of the 22 that did have SOPs had never revised them after their initial development (Nyika et al., 2009b). Moreover, although a training needs assessment conducted in Cameroon, Mali and Tanzania reported that 71 percent of REC members had received some training in research

ethics, it was also noted that the nature of training varied significantly and its actual impact on ethical review was unknown (Ateudjieu et al., 2010).

Literature also shows that researchers in all countries have varied perceptions about REC review. These views are often shaped by personal experiences with IRBs, and misperceptions are not uncommon (Lynn and Nelson, 2005). Some researchers view their IRB experiences as helpful, whereas others see IRBs as an impediment to research. One US survey found that about 26 percent of researchers abandoned potential research because they thought that the IRB would not approve their study (Wisner et al., 2011). However, 75 percent said that IRB review of research enhanced the protection of research participants and 66 percent believed that IRBs strengthened public trust in research (Wisner et al., 2011).

In a similar study conducted among scientists in South Africa on their experiences with ethics review, 42.6 percent indicated that their experiences were negative, whereas others described mixed experiences; only a minority (21.3%) stated that their experiences with IRBs were positive (Mamotte and Wassenaar, 2009). A cross-sectional study conducted in Uganda, however, found that 52.9 percent of the researchers thought that the IRB makes researchers more aware of ethical issues (Ibingira and Ochieng, 2010).

Study setting

Over the past decade, Botswana, like many of its neighbors, has established dual-track (institutional and national) mechanisms to provide oversight for all research undertaken in the country. The Botswana government requires that any person who wishes to conduct research in Botswana apply for a research permit, issued by government ministries according to the type of research. The Ministry of Health (MoH) is responsible for providing oversight for all health-related research studies and has established a national IRB which reviews all human health research that occurs in the country. The process of obtaining a permit involves submitting a research protocol, completed application form, and detailed curricula vitae for key researchers and other relevant documents to the ministry for review and approval. Ministries are additionally responsible for monitoring ongoing studies (Republic of Botswana, 2004).

At the same time, UB has also established an IRB to review all human research conducted by its staff members, students and affiliates, who then liaise with the relevant government ministries to obtain research permits. The UB IRB, housed within the Office of Research and Development (ORD), was established in 2005 to ensure that research conducted by the university community meets institutional, national, and international ethical standards. At the time of this study, the committee comprised 12 members (seven female and five male), with differing backgrounds including law, statistics, medicine, public health, philosophy, nursing,

social work, biological sciences, and psychology, and a community representative. The Chairperson of the committee was external to the university, and a majority of members had basic training in research ethics. The secretariat to the IRB comprised two individuals – an Assistant Director (Research Ethics) and an IRB Administrative Officer – who were both employed on a full-time basis. The Assistant Director (Research Ethics) also served as a member of the IRB. The IRB met once a month and discussed proposals requiring full committee review. The majority of proposals, which often qualified for expedited review, were reviewed by the secretariat and committee members outside of the IRB meeting. The IRB was also involved in offering workshops on research ethics and responsible conduct of research for the university community.

The university is the largest research institution in the country, with a goal of becoming known internationally as a 'research-intensive' university by the year 2021. It therefore recognizes the need to strengthen its capacity for research oversight, and coordinate its ethical review processes with national efforts, in preparation for institutional growth.

Methods

Ethical review

This study was reviewed and approved by IRBs of the Johns Hopkins Bloomberg School of Public Health and UB. Permission was also obtained from the Botswana Ministry of Health.

Study participants

This study was carried out at UB in Gaborone. UB respondents were asked to comment on both the IRB at UB and at the Ministry of Health, given their interaction with both committees. Study participants were academic staff members of UB who were, by virtue of their academic positions, expected to conduct research. The primary sampling units for this study were UB Faculties that specialized in human research; these included Faculties of Health Sciences, Medicine, Social Sciences, Business, Education, and the Department of Environmental Sciences. At the time of recruitment, there were approximately 440 academic staff members eligible for this study.

Data collection

Data for this study were collected via an online survey (SurveyMonkey[1]) which consisted of 61 items. The survey asked both closed- and open-ended questions and was divided into four sections: demographics, knowledge of IRBs and the

review process, challenges and experiences with IRBs, and opinions about IRB processes (see Table 1[2]).

A survey link was emailed to all 440 potential respondents inviting participation, accompanied by a disclosure page containing relevant consent information. A follow-up email was sent 2 weeks after the initial survey recruitment email; additional follow-up emails were sent at intervals of 2 weeks until no further responses were received over the course of a 1-month period. All data were collected from September to December 2010. Respondents were given the opportunity to be included in a prize draw through which two respondents received an academic textbook. Survey data were collected anonymously.

Analysis

Online survey data from Survey Monkey[1] were cleaned and entered into statistical software (SPSS® V 21, STATA 12, and Microsoft Excel) to calculate frequencies, percentages, and cross-tabulations. Analyses generated descriptive results and explored associations between demographics, knowledge about the ethical review process, experiences with research ethics committees, and opinions on whether the review process affects or influences the ability to conduct research in an ethical manner.

Results

Participants

Of the 440 eligible respondents, a total of 93 responses were received, of which 85 were considered complete and used for analysis. The 21 percent response rate is slightly low, but relatively consistent with other surveys administered online in LMIC settings (Chang et al., 2011; Hyder et al., 2004). The survey was designed such that there were skip patterns for some questions; therefore, the number of responses (n) varies for different questions. Gender representation was roughly equal amongst respondents (50.6% male), and most were affiliated with the Faculty of Education (40%), followed by the Faculties of Social Sciences (16.5%), Business (12.9%), Medicine (11.8%), and Nursing and Health Sciences (11.8%). About two-thirds had more than 5 years of research experience (Table 2[2]).

Researchers' knowledge of ethical review processes

When queried about their knowledge of the purpose of IRB review, nearly half of respondents (41.2%, $n = 85$) indicated that IRBs should be primarily concerned with 'the ethics of human research, the scientific validity of human

research, and the integrity of the research protocol' (Table 3[2]). Researchers with less than 10 years of experience and those representing the Faculty of Education, however, were significantly more likely to only indicate 'the ethics of human research' as a primary concern of IRBs reviewing protocols (p = .03 and .05, respectively).

A significant majority (62.4%, n = 85) of researchers indicated (correctly) that IRBs have the authority to approve, reject or request modifications of proposals submitted for review (Table 3[2]). Data also suggested that there was no uniform understanding of who has the authority and capacity to make a decision about whether or not to submit a protocol for review in the first place. Over 30 percent of respondents indicated that they made the determination themselves, whereas 17.6 percent indicated that an IRB administrator or member was often the source of this determination. Researchers with less than 10 years of research experience were more likely to indicate they were unsure who makes the determination to submit to an IRB (p = .03). Researchers from the Faculties of Medicine and Education were more likely to make the determination themselves, whereas researchers from the Social Sciences Faculty were more likely to indicate they did not know who should make the determination.

Many respondents (41.2%) indicated that both the researcher and IRB were responsible for ensuring the ethical conduct of studies, though 32.9 percent felt the onus rested solely on researchers (Table 3[2]). Respondents who identified as lecturers, and those with less than 15 years of experience in research, were more likely to identify researchers as solely responsible (p = .03 and .04, respectively).

Researchers' experiences with IRBs in Botswana

Most researchers who submitted protocols to the UB IRB (65.2%, n = 23) and to a government ministry (72.7%, n = 33) reported receiving approvals after initial submission, without requests for modification (Table 4[2]). Only two respondents reported having protocols ultimately rejected by the UB IRB; no protocols were reported rejected by a ministry. Nine of the 23 respondents (39.1%) felt the time required for the UB IRB to conduct reviews was average, whereas seven (30.4%) thought it took too long. Reviews performed by government ministries were considered by a majority to be shorter than average.

Nearly two-thirds of respondents (14/23) thought that feedback received from the UB IRB was useful or somewhat useful (Table 4[2]). Researchers were slightly less likely to report receiving useful feedback from government ministries, and about one-quarter did not receive any feedback from ministries.

Overall, slightly more than half of researchers reported having positive experiences in their interactions with both UB IRB and the government ministry (Table 4[2]). This finding was not associated with reports of positive or negative

IRB review outcomes (i.e. approvals or rejections). Researchers who indicated negative experiences with both IRBs were also more likely to comment that feedback was not useful, not received, or that the process had left them with a negative view of research ethics. Despite more than half of the sample reporting positive feelings about their interaction with both the UB IRB and government ministries, this did not necessarily translate into a more positive view of research ethics in general. Only about one-quarter of researchers who interacted with the UB IRB and ministry suggested that they had a more positive view of research ethics afterward. Over half (56.5% UB; 75.8% ministry) described no change in their perception of research ethics.

Researchers' opinions of the ethical review of research

A majority (62.4%) of researchers felt that a committee, like an IRB, is needed to review human subjects' research protocols under all circumstances (Table 5[2]). A large majority (71.8%) also felt that the process of ethical review of research protocols can help researchers better understand and appreciate research ethics. A similar number of respondents (74.1%) identified a need for researchers at UB to be trained in research ethics and IRB processes.

Discussion

This study was designed to elicit the perspectives of researchers at UB on the ethical review of research. Some of the key considerations identified by respondents include: the need for an IRB to review all human research protocols, high rates of approval after initial review at government ministries and UB, the need for research ethics training, and the capacity for ethics review processes to help researchers better understand and appreciate research ethics. We discuss each of these considerations in turn below and make recommendations for the university and for Botswana.

Researchers recognized the need for a committee, such as an IRB, to review all human research protocols

A significant majority (62.4%) of researchers felt that a committee, like an IRB, is always needed to review human subjects research protocols under all circumstances, and 12.9 percent indicated that IRB is needed sometimes. These findings are in line with international guidelines which require independent review of research involving human participants before initiating research (CIOMS, 2002; World Medical Association, 2013). However, our data also indicate some uncertainty about who has the responsibility to make determinations and whether

projects meet 'human subjects research' definitional criteria, and therefore whether they should be submitted for IRB review. This 'threshold' issue, which is not unique to Botswana or LMICs, can perhaps be decreased somewhat through the development of clear policies and decision tools that are communicated to researchers and other stakeholders in the country.

Researchers experienced high rates of approval at government ministries and UB

Almost three-quarters of protocols submitted to Botswana government ministries were reported to have been approved without requests for modifications, and none was rejected, whereas about two-thirds were approved without modifications by the UB IRB. The high approvable rate at UB could be attributed to the fact that the IRB was relatively 'new' at the time this study was conducted; hence most members were inexperienced with IRB review and had also not received-intensive training in research ethics. This observation was also made by Barchi et al. (2013), who pointed out that IRBs in Botswana are challenged with a lack of staff and committee members with knowledge and skills in research ethics. Barchi et al. (2015) also indicated that there is a necessity to train IRB members in Botswana in research ethics so as to strengthen their ability to review and monitor research protocols. They highlighted that ethics training initiatives for IRB members in Botswana mostly emphasize ethical principles and international guidelines as compared to ethical implications of particular medical technologies and research methodologies. Currently there are no minimum training requirements for UB IRB members. Though the UB Office of Research and Development periodically provides short workshops and seminars in research ethics to members, these are likely insufficient (Hyder et al., 2013).

The duration of review at government ministries was reported to have been shorter than at the UB IRB. The reported slightly higher rate of initial approval and faster turnaround time at the ministry level might, in part, be attributable to the fact that most protocols would have been reviewed and approved by the UB IRB before being submitted to government ministries for issuance of research permits. The shorter review periods were mostly experienced at the Ministry of Health and the Ministry of Education – two ministries that have a history of coordinating closely with UB IRB and that are willing to rely significantly on UB IRB for in-depth review of many protocols.

Researchers expressed the need for training in research ethics

UB researchers indicated that there was a need for training in research ethics and IRB processes. When asked who bears the responsibility of ensuring ethical

conduct in research, 41.2 percent indicated that both the researcher and IRB are responsible and 32.9 percent felt the onus rested solely on researchers. A majority of researchers, therefore, clearly understand that they play an important role in navigating potential and actual research ethics challenges. Our findings also indicate that researchers with less than 10 years of research experience were not fully conversant with the ethical review process. These respondents were also more likely to indicate that they were not sure who makes the determination to submit a protocol for IRB review, and thought that responsibilities for ethical conduct of research lay solely with the researcher. This suggests a particular need for targeted training on research ethics and IRB processes for junior and mid-career researchers, and refresher training for all researchers at regular intervals. These findings are consistent with recent recommendations to establish graduate training in bioethics and research ethics for UB students, and mandatory research ethics training for researchers so as to enhance research ethics capacity and awareness within the university (Hyder et al., 2013). Indeed, across sub-Saharan Africa, the teaching of research ethics has undergone a shift over the past 15 years from sporadic workshops to more organized and formal programs – certificate, master's, and doctoral (Ndebele et al., 2014). The Fogarty International Center of the US National Institutes of Health has played a key role in the establishment of these programs (Millum and Sina, 2014).

Researchers believe ethics review processes can help them better understand and appreciate research ethics

Most respondents believed that the very process of seeking ethical approval from IRBs can help researchers better understand and appreciate research ethics. This is consistent with a study conducted in Uganda to assess the attitudes and perceptions about research and ethics committees, which found that 52.9 percent of the researchers thought that RECs make researchers more aware of ethical issues (Ibingira and Ochieng, 2010). Nevertheless, most researchers surveyed in this study indicated that their experiences with the UB IRB and ministries did not change their outlook on research ethics. Perhaps this is because a sizeable majority of proposals were approved without modifications, leaving researchers with little evidence as to what the IRB considered and what ethics issues may be potentially relevant to the study. It is noteworthy that approximately one-quarter of respondents did report having a more positive view of research ethics after undergoing ethical review.

The general belief among respondents that IRBs have the capacity to fulfil a relatively broad mandate, which may include increasing understanding for research ethics within the institution, is of interest. This belief may contrast with other settings where IRBs are expected to serve more narrowly defined roles. Future efforts

to advance research ethics in Botswana may include further training of IRB office personnel, committee members, and ethics scholars to develop additional skills in research ethics consultation to open new pathways for communication between the IRB office and the research community.

Recommendations

The University of Botswana has committed valuable resources, both financial and human, to support its system for ethical review in recognition of the essential role the IRB plays in a research-intensive institution. Efforts to further strengthen UB's system for ethical oversight of research might include developing more stringent policies to guide the conduct of research involving human participants. Although the university has a policy on ethical conduct of research (University of Botswana, 2004), this policy does not mandate that researchers submit to the UB IRB for ethical review, nor does it define what types of activities qualify as human subjects research. In addition, the policy does not address most contemporary issues in research ethics.

The university should also consider developing research ethics courses at the graduate level and mandatory training for researchers to help build confidence and capacity outside the IRB in identifying and addressing ethical issues. Similarly, there is a need to establish minimum required qualifications (inclusive of research ethics training) for IRB members, and offer refresher courses to members at regular intervals so as to ensure that they are up to date with current issues in research ethics and competent to conduct ethics review. UB IRB members could also be provided incentives or other meaningful institutional recognition to further enhance their work, which is currently a volunteer endeavor, especially if they are to take on particular training or consultation-related responsibilities for the benefit of the community of researchers.

Finally, given that the ministry-level review generally proceeded quickly and with few comments for researchers, the question emerges whether the university and government ministries responsible for issuing research permits should further engage to identify where the review efforts of each institution would be best focused, and to determine whether reliance arrangements can be expanded and formalized. Botswana has the opportunity to lead the development of a model for shared national-institutional review.

Limitations

The response rate for this study was fairly low, but relatively consistent with other surveys administered online in LMIC settings. The low response rate to certain questions may be indicative of the general low response rate. For example, when

asked about having ever submitted a protocol to UB IRB, more than half of the respondents did not respond. This lack of response may be because of an unwillingness to expose non-compliance with the IRB. Given the response rate, it remains unclear to what degree the findings can be generalized to the wider community of researchers at UB. In addition, data were self-reported and were not confirmed through observation or document review. Our objective, however, was to capture researchers' opinions, perceptions, and knowledge of basic elements of the ethical review system in Botswana, and the study was designed to achieve this aim. As researchers are key stakeholders in any ethics review system, their perceptions are important to understand and take into account, even if they do not align perfectly with actual occurrences.

Although data reported herein were collected several years ago (in 2010), no studies have since documented researchers' experiences with and perceptions of the ethical review of research in Botswana. Nevertheless, it is important to acknowledge that perceptions can change and that UB has engaged in capacity-strengthening partnerships over the past several years, which may have impacted the perceived function and value of research ethics and ethical review. Anecdotal experiences, however, suggest that many researchers are still not entirely familiar with the IRB submission process and struggle with writing high-quality proposals. We therefore hope this study will help to highlight some of the local challenges that can benefit from further examination and targeted interventions, e.g. training and policy/resource enhancement to strengthen IRB submissions. More in-depth qualitative research could support the development of a deeper understanding of particular associations identified in this study, and perhaps gather additional views on IRB oversight of research in Botswana.

Conclusion

In contexts where IRBs have been established relatively recently, such as in Botswana, it can be important to document the perspectives of researchers in order to align expectations with capabilities, and identify areas where IRBs can improve operations. Future efforts to advance research ethics and ethical review in Botswana should include establishing research ethics training requirements and courses for researchers, increasing investment in IRBs and their training, further developing institutional and national research ethics policies, and formalizing agreements between IRBs and others involved in research oversight in the country to support coordinated review.

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Notes

1. SurveyMonkey. *SurveyMonkey Software*. Available at: https://www.surveymonkey.com.
2. Tables 1–5 may be viewed online.

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