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Enhanced REC collaborative review through video-conferencing

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As international collaborative health research activities increase, building research ethics committees (REC) infrastructure and capacity in low- and middle-income countries for efficient and thorough review of research protocols becomes more critical, especially in sub-Saharan Africa. International investigators may face multiple challenges when conducting research in these settings, an important one being the length of time involved in securing REC review and approval. We discuss an approach to the problem that involved organisation of 'rapid review' REC sub-committees who met via video-conference for collaborative review of research protocols.

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There has been a dramatic expansion of biomedical research in low- and middle-income countries (LMICs) in the last few decades, much of it designed in high-income countries, and the workload of research ethics committees (RECs) and/or institutional review boards (IRBs) has grown exponentially.[1] Since many LMICs have limited capacity in research ethics and bioethics, there is widespread concern that without well-designed training programmess and substantive capacity-building initiatives there could be an increase in vulnerability to exploitative research.[2] Examining resource needs in Africa, researchers found that 97% of REC members believed they had inadequate training in ethics and management of HIV vaccine trials and 80% believed they had inadequate training in health research ethics.[3]

Sub-Saharan Africa has an admirable history related to the establishment of RECs and protecting human subjects involved in research activities; several reports suggest that a majority of countries have some procedures in place for ethical reviews.[4,5] We do know from the Kass case study[4] that South Africa (SA) established a REC in 1967 and at least eight other committees had been established since 2002. That said, during this time period and beyond, the African scientific community has been challenged with a variety of ethical issues. These include, but are not limited to onerous REC workloads, inadequate training, more sophisticated research protocols requiring greater need for expert review, and lack of resources to secure appropriate ethical reviews.[6-9] Tanzanian researchers and ethics review committee members have expressed concerns about the validity of applying international ethical principles that may be seen as not in alignment with the Tanzanian culture.[10] There continues to be a need for bioethics training in Africa, especially in the context of vaccine trial preparedness, be it HIV, TB, malaria or any of the other major endemic health problems impacting morbidity and mortality. International investigators may face major challenges when doing research in Africa, and one of the first to arise is ensuring that ethical review of a study meets international guidelines (i.e. Declaration of Helsinki (2013), CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), Good Clinical Practice, and the Federal regulations that apply to research sponsored by US government agencies). Challenges have also been encountered regarding the appropriate ethical handling of human specimens and research data that are sent from Africa to high-income countries for further processing and storage, especially since there is a lack of uniformity in regulations across country borders.[11]

Building research capacity involves a critical focus on the REC; enhanced capacity will benefit not only REC members, but also all stakeholders including principal investigators, research sponsors, and host communities. Over the past 26 years, the Fogarty International Center, part of the US National Institutes of Health, has supported research ethics capacity throughout the world and especially in Africa; this has significantly broadened the literature related in the field.[12-14] Some of the ethical areas that are generally not well developed include appropriate management of vulnerable populations, the powerful manifestations of conflict of interest, confusion regarding standards of care, and the role and responsibilities of the investigator.[15] Beyond these areas, there is evidence that many African RECs have inadequate financial support and find it difficult, given the economic realities in their countries, to insist on more funding for committee education and administrative support.[7,16] Sociocultural and linguistic differences, compounded with variations in history, wealth, politics,

and power relations between cultures can be major roadblocks to building research capacity in any resource-limited setting, especially in sub-Saharan Africa.[17]

As LMICs experience increases in research activities, it is important that funding institutions and the universities and/or organisations where the research will be conducted work collaboratively on ethical review matters so that delays do not adversely impact research progress. Indeed, the Institute of Medicine notes that duplicative review may actually adversely impact human subject protection.[1] Several options that could be considered include jointly developing standard operating procedures for international collaborative research that allow for parallel or simultaneous submission of protocols,[17] and using a central IRB (CIRB) for multicentre research whereby local IRBs may rely on the CIRB for primary review and only conduct a facilitative review if there are ethical issues related to local cultural norms.[18] It should be noted, too, that the use of electronic review management systems could streamline the IRB review process in African countries, perhaps supplementing the video-conference modality that was used for this project.

We believe it is critical that these issues need to be better understood and incorporated into any research ethics capacity-building effort. Research can continue, but without continuing improvement of the research ethics infrastructure, any lessons learned from reviewing research may not be translated to consistent practice. The overall goal of our project was to establish new and strengthen existing expertise in IRB management and training among research scientists, faculty, healthcare providers and other professionals at Muhimbili University of Health and Allied Sciences (MUHAS) and throughout Tanzania.

The problem

The length of time involved in securing IRB/REC approval is an important factor that investigators must consider when planning research in LMICs, and this must be incorporated in the time-line for research projects. At one SA REC during the period 1997 – 1999, 388 research protocols were reviewed and the average turnaround time for processing a protocol was 96 days.[7] Through a needs assessment of 31 RECs across Africa, Nyika *et al.*[5] found that the average time for a protocol review was 2 months. Cleaton-Jones discusses issues related to the increase in both REC applications and complaints from researchers about the time involved in obtaining approval for research, much of which was due to staffing issues, revisions required for applications, etc., and addresses the need to estimate REC workloads and invest in staffing resources as approaches that could be used.[19,20] With new and evolving health crises such as the most recent Ebola virus disease (EVD)[21] and the current widespread Zika virus outbreaks, special guidance must be considered for rapid review and approval for treatment and research in this context. Further, this becomes an even more important issue when experimental drugs and/or vaccines are being used before they have been proven efficacious in humans, especially in countries whose RECs may not have dealt with such issues.[22] During this outbreak, the World Health Organization released multiple statements and other guidance related to the ethical criteria surrounding care and treatment – the one on 5 September 2014 offering four critical elements concerning treatment and research.[23]

Our approach to the problem

To improve the ethical and cultural competencies of the IRB/REC at both Dartmouth and MUHAS and streamline the otherwise serial protocol review and approval process, we organised 'rapid review' committees (RRC) at both institutions. Both of these RRCs had the appropriate expertise and members in attendance to review each protocol and were capable of exercising the authority of an IRB established under the Federal-Wide Assurance. New and/or modifications of protocols for studies being done in Tanzania by researchers at Dartmouth and MUHAS were assigned to these committees for their review and approval. These studies involved a double-blind, randomised clinical trial of a vaccine being tested for the prevention of disseminated tuberculosis in HIV patients, and a study of hearing loss in HIV-positive and HIV-negative subjects. Five video-conference meetings were held between February 2011 and March 2012. To accommodate for the difference in time zones (+8 hours in Tanzania), they began at 07h00 (USA) and 15h00 (Tanzania) and lasted approximately 1.5 hours. These joint meetings, the first ever done at Dartmouth and MUHAS, were conducted at Dartmouth's Center for the Advancement of Learning (DCAL) and the Tanzania Global Development Learning Center (TGLD), using state-of-the art facilities and equipment. Both DCAL and TGLD use the H.323 Protocols Suite technology that provides a foundation for audio, video, and data communications across IP-based networks, including the Internet. DCAL offers video-conference services to faculty and staff at no cost; the TGLD in Dar-es-Salaam charged a fee of USD 250 per session which, if not covered by grant funds or other means, could be prohibitively expensive for a LMIC. In 2014 MUHAS acquired its own video-conference system that has been installed in a large modern room in the university library and these services are now available free of charge. This was an important step in strengthening the REC capacity at the institution.

The first video-conference was an introductory session for members to meet one another and discuss their respective procedures. For the other four sessions, a primary reviewer representing each committee was responsible for presenting a summary of the research protocol, its ethical issues, and leading the discussion that followed. The documents required by each committee (protocols, consent forms, etc.) were shared electronically 2 weeks in advance of each video-conference. The agenda for each session included time for an assigned member of one of the committees to present a summary report of a journal article or other information, and lead a brief discussion as continuing ethics education. Consensus voting on approval or required study modifications took place during the video-conference and each committee was responsible for submitting individual letters to the PI of the studies that were reviewed. We did not seek ethics approvals from the committees since they had agreed to participate in the video-conferences as part of the grant activities, so they deemed ethical approval was not necessary.

Programme evaluation

An evaluation of the joint video-conference meetings was conducted using SurveyMonkey. Members of the rapid review committees at Dartmouth and MUHAS were asked to answer a series of ten questions. The questions and their responses are shown in Table 1.

Table 1. Evaluation of the joint video-conference meetings, conducted using SurveyMonkey

Question	Response
This series of joint video-conference review sessions was considered an innovative element of the work plan. How do you rate the sessions overall from an IRB/REC perspective?	43% said very helpful, 36% said helpful, and 21% said somewhat helpful
All documents for the sessions were sent electronically. Was this the best way to share materials?	93% said yes
Did you have enough time to review the materials before the video-conference?	93% said yes
A primary reviewer from Dartmouth and MUHAS was designated and he or she was responsible for presenting each committee's discussion points. Was this useful?	100% said yes
Each video-conference included a time for continuing education. How would you rate this activity?	54% said very helpful, 31% said helpful, and 15% said somewhat helpful
Each video-conference was scheduled for 1.5 hours. Was this amount of time adequate to complete the agenda?	93% said yes and 7% suggested 2 hours would be better
What would you say was the most beneficial part of the sessions?	The benefits of the continuing education discussions, the availability for live interaction, understanding the differences between the two committees, better understanding the challenges faced by researchers in Tanzania, ability to share perspectives from each IRB, seeing issues approached differently but achieving the same outcome
What would you say was the least beneficial part of these sessions?	Making sure there is enough time for discussion of differences in approaches and priorities, expensive venture and donor dependent (so perhaps not practical), discussing only one proposal potentially not cost-effective, challenging logistics, time differences, travel time for MUHAS to get to the video-conference session
Would you like these video-conference meetings to continue, if funding were available?	93% said yes
Other comments?	The groups were a little large – for optimal collaboration perhaps no more than five people at each site, ethical issues presented in the proposed research were not common to both committees, sessions did not seem to impact on IRB determinations, joint committee video-conferences a superior method of review for studies being conducted in disparate areas of the world, and reciprocal education or innovation needed by members of both committees

In summary, the evaluation found that the video-conference sessions were helpful to very helpful (100%); electronic document sharing was helpful and sufficient (93%); having primary reviewers at each site was appropriate (100%); and the continuing education component was very helpful (85%).

Lessons learned

The major benefits of these collaborative IRB video-conferences were identified as:

- continuing ethics education reflecting the US and Tanzanian perspectives
- live interactions and discussions of important research protocols in a timely fashion
- an effective method for understanding committee differences, challenges, and perspectives on how reviews can be performed but achieve the same goals.

One useful suggestion resulting from the project was to designate one video-conference for a discussion of the differences in US and Tanzanian committee approaches and priorities. The overall assessment by all participants was that collaborative video-conferencing is a superior method for review of studies being conducted in disparate areas of the world and is especially effective in LMICs.

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References

1. Kotsis SV, Chung KC. Institutional review boards: What's old? What's new? What needs to change? Plast Reconstr Surg 2014;133(2):439-445. DOI:10.1097/01.prs.0000436846.00247.73
2. Singer PA, Benatar SR. Beyond Helsinki: A vision for global health ethics – improving ethical behaviour depends on strengthening capacity. BMJ 2001;322(7289):747. DOI:10.1136/bmj.322.7289.747
3. Milford D, Wassenaar D, Slack C. Resources and needs of research ethics committees in Africa: Preparations for HIV vaccine trials. IRB: Ethics Hum Res 2006;2(2):1-9.
4. Kass NE, Hyder AA, Ajuwon A, et al. The structure and function of research ethics committees in Africa: A case study. PLoS Med 2007;4(1):26-31. DOI:10.1371/journal.pmed.0040003
5. Nyika A, Kilama W, Chilengi R, et al. 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(3):189-193. DOI:10.1136/jme.2008.025189
6. Nyika A, Kilama W, Tangwa GB, Chilengi R, Tindana P. Capacity building of ethics review committees across Africa based on the results of a comprehensive needs assessment survey. Dev World Bioeth 2009;9(3):149-156. DOI:10.1111/j.1471-8847.2008.00243
7. Dada M, Moorad R. A review of a South African research ethics committee. Ind J Med Ethics 2001;9(2):58-59.
8. Millum J, Sina B, Glass R. International research ethics education. JAMA 2015;313(5):461-462. DOI:10.1001/jama.2015.203
9. Silaigwana B, Wassenaar D. Biomedical research ethics committees in sub-Saharan Africa: A collective review of their structure, functioning, and outcomes. J Empir Res Hum Res Ethics 2015;10(2):1-16. DOI:10.1177/1556264615575511
10. Ikingura JKB, Kruger M, Zeleke W. Health research ethics review and needs of institutional ethics committees in Tanzania. Tanzania Health Res Bull 2007;9(3):154-158. DOI:10.4314/thrb.v9i3.14320
11. Sathar MA, Dhai A. Laws, regulations and guidelines of developed countries, developing countries in Africa, and BRICS regions pertaining to the use of human biological material (HBM) in research. S Afri J Bioethics Law 2012;5(1):51-54.
12. Millum J, Grady C, Keusch G, Sina B. Introduction: The Fogarty International Center research ethics education and curriculum development program in historical context. J Empir Res Hum Res Ethics 2013;8(5):3-16. DOI:10.1525/jer.2013.8.5.3
13. Ndebele P, Wassenaar D, Benatar S, et al. Research ethics capacity building in sub-Saharan Africa: A review of HIV Fogarty-funded programs 2000-2015. J Empir Res Hum Res Ethics 2014;9(2):24-40. DOI:10.1525/jer.2014.9.2.24
14. Ali J, Kass NE, Sewankambo NK, White TA, Hyder AA. Evaluating international research ethics capacity development: An empirical approach. J Empir Res Hum Res Ethics 2014;9(2):41-51. DOI:10.1525/jer.2014.9.2.41
15. Sugarman J, Abayage P, Aborigo RA, et al. Ethical oversight of multinational collaborative research: Lessons from Africa for building capacity and for policy. Res Ethics Review 2007;3(3):84-86. DOI:10.1177/174701610700300305
16. Chilengi R. An ethics perspective on responsibility of investigators, sponsors and research participants. Acta Tropica 2009;112S:S53-S62. DOI:10.1016/j.actatropica.2009.08.004
17. Sidle JE, Were E, Wools-Kaloustian K, et al. A needs assessment to build international research ethics capacity. J Empir Res Hum Res Ethics 2016;1(2):23-38. DOI:10.1525/jer.2006.1.2.23
18. Millum J, Menikoff J. Streamlining ethical review. Ann Int Med 2010;153(10):655-657. DOI:10.7326/0003-4819-153-10-201011160-00008
19. Cleaton-Jones P. Applications and secretariat workload at the University of the Witwatersrand human research ethics committee (medical) 2002 - 2011: A case study. S Afri J Bioethics Law 2012;5(1):38-44.
20. Cleaton-Jones P, Grossman ES. Things may not be as expected: Surprising findings when updating workload at the Wits human research ethics committee (medical). S Afri J Bioethics Law 2015;8(1):14-21. DOI:10.7196/SAJBL.339
21. Dhai A. The Ebola crisis: Ethical challenges in the African context. S Afri J Bioethics Law 2014;7(2):42-23. DOI:10.7196/SAJBL.359
22. Saxena A. Ebola virus disease outbreak: Incorporating ethical analysis into the health system response. Ind J Med Ethics 2014;11(4):200-202.
23. World Health Organization (WHO). Statement on the WHO Consultation on Potential Ebola Therapies and Vaccines. Geneva: WHO, 2014. http://www.who.int/mediacentre/news/statements/2014/ebola-therapies-consultation/en/ (accessed 23 July 2015).