



CAPACITY BUILDING OF ETHICS REVIEW COMMITTEES ACROSS AFRICA BASED ON THE RESULTS OF A COMPREHENSIVE NEEDS ASSESSMENT SURVEY

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Keywords

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ABSTRACT

A needs assessment survey of ethics review committees (ERCs) across Africa was conducted in order to establish their major needs and areas of weaknesses in terms of ethical review capacity. The response rate was 84% (31 of 37 targeted committees), and committees surveyed were located in 18 African countries. The majority of the responding committees (61%) have been in existence between 5 and 10 years; approximately 74% of the respondents were institutional committees, with the remainder being either national (6/31) or regional (2/31).

In terms of the ethical review process, nine of the 31 committees that responded did not have standard operating procedures (SOPs), and seven of the 22 that did have SOPs had never revised them after their initial development (an average period of three years). Of the 31 committees, 10 operated without any ethical guidelines. Many of the committees (13/30) met once per month, and the number of proposals reviewed annually varied, ranging from five to over 100. All respondents relied on paper-based data management and archiving systems.

Overall, the survey identified the major constraints on ERCs as lack of office equipment, outdated or lack of SOPs, lack of electronic data management systems, inadequate resources, lack of or insufficient expertise on the committees, and poor recognition of the importance of the role of the committees. Consequently, the authors are addressing the identified needs and weaknesses through the Bill and Melinda Gates Foundation-funded capacity building project. The impact of the intervention project will be assessed during and at the end of the four-year longitudinal project.

INTRODUCTION

Health research has undergone unprecedented changes and expansion in both the developed and developing worlds over the past few decades. Although the dynamics and growth have been generally beneficial to humankind, the changes have led to an increase in the workload of ethics review committees (ERCs) mandated to protect the increasing numbers of human subject participants in

health research. In the United States (US), the challenges affecting ERCs have led to a sense of crisis among concerned stakeholders.¹ Burman et al. reported an increase in regulatory actions taken by the US Food and Drug Administration (FDA) against institutional ethics

¹ W.J. Burman et al. Breaking the Camel's Back: Multicenter Clinical Trials and Local Institutional Review Boards. *Ann Intern Med* 2001; 134: 152–157; R.J. Levine. Institutional Review Boards: A Crisis in Confidence. *Ann Intern Med* 2001; 134: 161–163.

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committees for failing to abide by various FDA operational requirements from one committee in 1997 to 14 committees in 1999.²

Although the increasing trend of collaborative research in Africa is welcome news, it also means that the existing ERCs in Africa have to review a lot more proposals; the studies are also a lot more complex than the types of studies that most African ERCs are familiar with. The complexity of the studies is due to a number of factors, including new technological developments, the emergence of new diseases, and the shift from local research projects to international collaborative projects that involve participants and collaborating researchers drawn from different countries with diverse cultural and socio-economic backgrounds.

International collaborative research usually involves funding from developed countries and shipment of samples to high-tech laboratories in developed countries; collaborating institutions in developing countries generally have inadequate expertise and technology to perform some of the more complicated research procedures. For instance, nowadays ERCs have to grapple with controversial issues, such as the genetic manipulation of human embryos, that were unheard of a few decades ago.³ From the genetic engineering of plants and animals, some scientists are now working in the controversial field of genetic engineering of human beings. Technological developments have enabled hypothesis-free mapping of the human genome to be performed as a new approach to genomic epidemiological studies of complex diseases. Another example is the advent of clinical trials of candidate vaccines and drugs, which were previously uncommon in Africa but are now gradually increasing as efforts to address the 10/90 gap,⁴ and the high disease burden of Africa, intensify.

The ultimate goal of health research is to improve preventive, diagnostic and therapeutic methods, or to develop new ones. It should be acknowledged that the development or testing of new disease interventions must be carried out on humans. However, historically some research participants have been exposed to unethical research, and concerns have been raised about some

studies conducted in developing countries.⁵ In addition, products of health research may be unaffordable to the poverty-stricken populations that participate in the research. In light of the generally poor health delivery systems, lower levels of education, and the poverty of communities and governments, it has become imperative that the capacity of ERCs in Africa to adequately review protocols and subsequently monitor studies effectively be assessed and, if need be, strengthened.

To date, not many empirical studies on ethical review capacity building in Africa have been reported. The Pacific Institute for Research and Evaluation (PIRE), a US-based organization, reported a strategy used to strengthen the capacity of the University of Liberia in an international collaborative research involving the two institutions.⁶ The Johns Hopkins Fogarty African Research Ethics Training Program, which has trained a number of scholars from African countries, reported on the status of 12 ERCs that were affiliated with some of the trainees.⁷ Kirigia et al. undertook a survey of the existence of national ERCs in African countries, and reported that 36% (10/28) of respondents in their survey did not have national ERCs.⁸ In light of the paucity of comprehensive data on needs and capacity building of ERCs in Africa, we conducted a survey aimed at identifying the weaknesses of ERCs across Africa. Most importantly, a follow up intervention, based on the baseline survey data, is being implemented in order to address the identified needs of the committees.

METHODOLOGY

Instrument

After obtaining ethical approval to conduct the needs assessment survey, a questionnaire was designed and

² Burman, *ibid*.

³ M. Ritter. 2008. *Genetically Modified Human Embryo Stirs Criticism*. Online: Associated Press (New York, NY): 12 May. Available at: http://ap.google.com/article/ALeqM5jayE9Ru_1pu1_b3RQuKGszU6409QD90KBJH00 [Accessed 14 May 2008].

⁴ See Global Forum for Health Research (GFHR). 2000. *10/90 Report on Health Research 2000*. Geneva: GFHR. Available at: http://www.globalforumhealth.org/filesupld/1090_report_00/00ExSS.pdf [Accessed 2 Jun 2008].

⁵ P. Lurie & S. Wolfe. Unethical Trials of Interventions to Reduce the Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries. *N Engl J Med* 1997; 337: 853–856; A.J. London. Justice and the Human Development Approach to International Research. *Hastings Cent Rep* 2005; 35(1): 24–37.

⁶ S.B. Kennedy et al. Developing Capacity to Protect Human Research Subjects in a Post-Conflict, Resource-Constrained Setting: Procedures and Prospects. *J Med Ethics* 2006; 32: 592–595.

⁷ A.A. Hyder et al. A Case Study of Research Ethics Capacity Development in Africa. *Acad Med* 2007; 82: 675–683; N.E. Kass et al. The Structure and Function of Research Ethics Committees in Africa: A Case Study. *PLoS Med* 2008; 4: e3. Available at: <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0040003&ct=1> [Accessed 31 May 2008].

⁸ J.M. Kirigia, C. Wambebe & A. Baba-Moussa. Status of National Research Bioethics Committees in the WHO African Region. *BMC Med Ethics* 2005; 6: 10–16.

piloted in Ghana, Malawi and Tanzania. This was done to ensure that there were no ambiguities. Revisions were carried out in accordance with the recommendations garnered from the questionnaires. The questionnaire was also translated into French and then back-translated by bilingual experts in order to ensure accuracy and avoid ambiguity. The final questionnaire had 103 questions divided into sections covering establishment of the committees, composition of the committees, operations of the committees, the ethical review process, constraints on the committees, and training needs of committee members.

Target ERCs

Based on a database of health research institutions and ERCs generated from past and ongoing workshops, and networking, and other capacity building activities in Africa, thirty-seven institutions were identified, from which an inventory of contact details of contact persons was developed. Although the intention was to survey as many African ERCs as possible, efforts to include some countries, especially those located in the central region of Africa, were unsuccessful. The French version of the questionnaire was administered to respondents from francophone countries.

Surveyors

In order to conduct the needs assessment survey, surveyors who were ethicists in various African countries were allocated ERCs. A total of six surveyors from six different African countries were assigned countries, which they had to visit in order to administer the questionnaire physically. Two of the six surveyors were bilingual in French and English, and they were assigned to francophone countries. Prior to the visits, the surveyors emailed the questionnaire to the ERC chairpersons or administrators to allow the contact person to review the questionnaire in preparation for a scheduled interview. The questionnaires were then administered face-to-face, after which both the hard and electronic copies were submitted for analysis.

RESULTS

Response rate

The collected data were analysed using STATA 10 (Stata Corporation, College Station, TX). The response rate was 84% (31/37) and the surveyed institutions were

located in 18 different African countries. The countries included francophone and anglophone countries; these are shown in Figure 1.

Description of the ERCs

The majority of the surveyed ERCs (22/31) were institutional committees, while seven were national and two were regional. Institutional ERCs are committees established by health research institutions or academic institutions. Membership ranged from three to 21 members; the mean number of members per committee was 11. In terms of guidelines and standard operating procedures (SOPs), 10 of the 31 committee respondents reported that they operated without national ethical guidelines, while nine reported that they did not have SOPs. Although respondents considered training, upon joining the ERCs, to be important, 11 of the 31 committees did not offer any training to new members, and 17 lacked continuing training for members. Other features of the committees are shown in Table 1.

Resources available to the ERCs

Table 2 shows the resources available to the surveyed committees. It is worth noting that although most of the committees had functional offices, all had poor data management and archiving systems in place. In addition, more than half of the committees lacked full-time secretarial support.

Performance and ethical review process of the ERCs

Table 3 summarizes aspects of ERCs pertaining to the volume of work and the ethical review process. The average period of review of a protocol is two months, and 16 of the 23 committee respondents reported that less than 10% of protocols submitted in 2006 were rejected. The rejections were mainly for methodological reasons, followed by ethical reasons. Where protocols were rejected for methodological reasons, experimental designs were flawed in one way or another and were not appropriate for the research questions the researchers sought to answer. It would be unethical to let participants carry the burden of poorly designed research as the data generated would not contribute to the improvement of the health of individuals. Where protocols were rejected for ethical reasons, some aspects of the proposed recruitment and/or experimental procedures violated some ethical principles, namely principles of autonomy, beneficence,

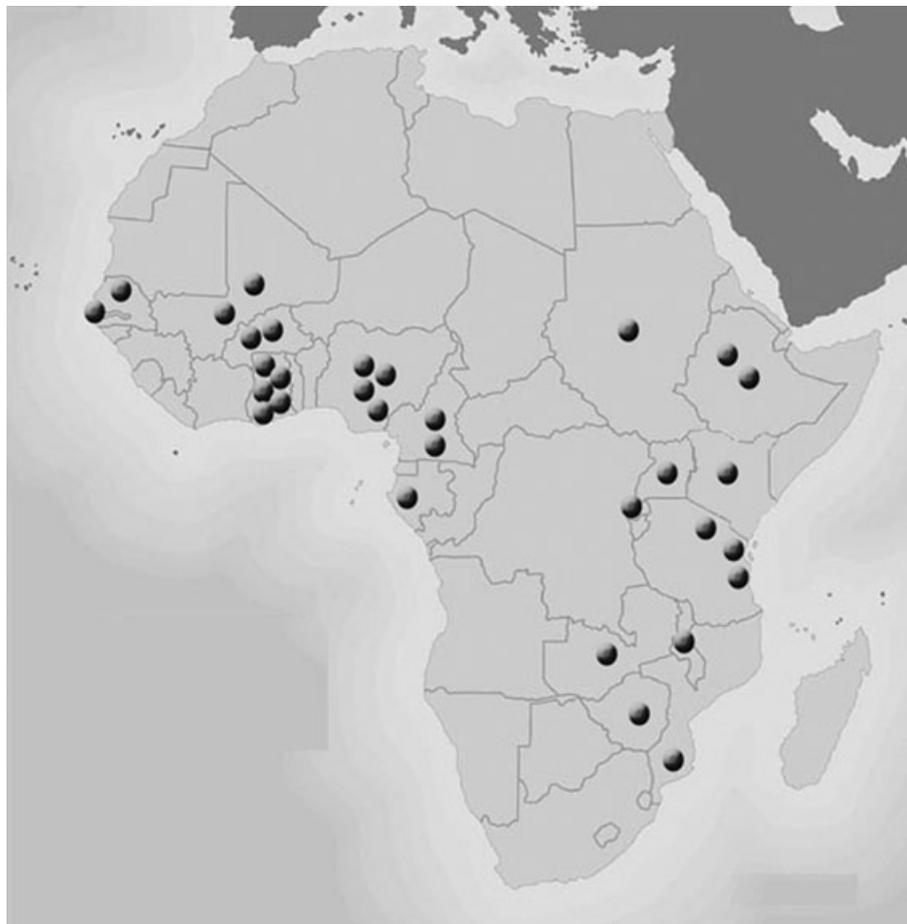


Figure 1. Map of Africa Showing Countries Surveyed.

non-maleficence and justice. This means that although the experimental designs were scientifically sound, there were some non-scientific pertinent issues surrounding the proposed studies that were deemed to be unethical. For instance, if researchers proposed to conduct a phase I trial to test a vaccine for a disease that did not affect the population from which the participants were to be drawn, then such a study would violate the principle of distributive justice because the participants would carry the burden of being experimented on when the potential post-study benefits would not be relevant to their needs.

For most of the committees, the review process involved all committee members, and decisions were made through consensus agreement. ERCs that relied on consensus decision making used that method each time they reviewed protocols, whereas those that did not make decisions by consensus had variable methods of deciding, depending on the outcome of their discussions as committees. Thus, after debating a protocol under review they may discuss and agree to decide by consensus, while for another protocol they may choose to decide by open majority voting.

More than 50% of committees (16/30) did not inspect approved studies, a loophole that could enable protocol violation to go on unnoticed. Inspection of approved studies entails field visits by members of the relevant ERC to the sites of approved research projects in order to minimise the risk of deviations from the approved protocols. Essential project documents such as informed consent forms, serious adverse event reports and loss to follow-up reports are inspected. In addition, experimental procedures are observed, such as the screening of prospective participants, the process of obtaining informed consent, and the nature of interactions between participants and the research team. Additional information can also be obtained from participants through exit interviews.

Workload of surveyed ERCs

Only one, of the 31 respondents, did not provide information regarding the frequency of their meetings. However, out of the 30 ERCs that did respond, 13

Table 1. Description of Surveyed Ethics Review Committees (ERCs)*

Characteristic	Number of ERCs
<i>Age of ERC (years)</i> <i>n = 28</i>	
<1	1
2-4	3
5-6	9
7-10	8
11-20	3
21+	4
<i>Status of ERC</i> <i>n = 31</i>	
Institutional	22
National	7
Regional	2
<i>Legal basis of ERC</i> <i>n = 19</i>	
Act of Parliament	4
Institutional regulation	12
Academic board/ministerial directive/non governmental organization	3
<i>Existence of national guidelines on ethical review</i> <i>n = 29</i>	
Yes	19
No	10

* Some committees did not respond to all questions.

Table 2. Resources Available to Ethics Review Committees (ERCs)*

Resources	Number of ERCs
Office space	22/29
Computer	22/28
Office furniture	22/28
Printer	22/28
Internet access	20/28
Email facility	19/28
Telephone	18/28
Filing cabinets	18/27
Electronic data management and archiving system	0/31
Full-time secretarial support	12/27

* Some committees did not respond to all questions.

reported that they met monthly to review protocols. As shown in Table 4, the number of protocols reviewed annually was very variable, ranging from five to over 100 for the most active committees (5/28).

DISCUSSION

Our study has gathered important information on the status and needs of ERCs in Africa; to the best of our

Table 3. Performance and Ethical Review Process of Ethics Review Committees (ERCs)*

Average time for processing a protocol	Number of ERCs (n = 26)
1 month	11
2 months	12
3 months	3
<i>Proportion of protocols disapproved in 2006</i> <i>Number of ERCs (n = 23)</i>	
Less than one tenth	16
Less than one quarter	5
Less than one third	2
<i>Major reason for disapproval</i> <i>Number of ERCs (n = 23)</i>	
Methodological	15
Ethical	6
Lack of sufficient funding	1
Limited capacity to implement protocol	1
<i>Who reviews protocols before meeting</i> <i>Number of ERCs (n = 29)</i>	
All members	14
Majority of members	7
Primary reviewer(s)	5
Presentation during ERC meeting	1
Only a few	1
Expert secretary	1
<i>How are decisions reached</i> <i>Number of ERCs (n = 30)</i>	
Open majority vote	2
Consensus	26
Discussion	2
<i>Interactions/feedback/monitoring</i> <i>Number of ERCs</i>	
Committee invites investigators for clarifications	24/31
Procedures for monitoring approved research in place	19/30
Committee conducts any study inspections	14/30
Procedures for reporting serious adverse events in place	21/28
Committee records cases of protocol violations	9/29
ERC ever disagreed with ethics committee in collaborating country	6/29

* Some committees did not respond to all questions.

knowledge this is the largest and most comprehensive report in this area. It is evident from the survey that ERCs in Africa operate in conditions that hinder their effectiveness in protecting the safety and welfare of research participants. In the wake of the increased workload, the committees reported that they are overwhelmed by the number and complexity of studies to be reviewed, which is further compounded by inadequate training of the committee members.

Four of the ERCs surveyed review up to 100 protocols annually, which is an average of 8.3 protocols each month; some of these ERCs meet weekly. Given that

Table 4. Workload of Surveyed Ethics Review Committees (ERCs)*

Meeting frequency	Number of ERCs (n = 30)
Once per week	2
Once per month	13
Once every 2 months	4
Once every 3 months	2
Once every 4 months	2
Once every 6 months	1
Irregularly	6

Number of protocols reviewed annually	Number of ERCs (n = 28)*
1–10	3
11–20	6
21–30	3
31–40	3
41–50	0
51–60	3
61–70	0
71–80	1
81–90	0
91–100	4
+100	5

* Some committees did not respond to all questions.

nearly all staff are part-time volunteers who are invariably busy in their respective professions, there may be a case for expanding the membership of committees so that reviews may be carried out by their members in rotation. It would otherwise be difficult to guarantee that part-time members of ERCs are able to review protocols thoroughly and render the required protection of human subjects. For such overloaded ERCs, relying on volunteers who may be continually busy with their core duties at their places of employment, the overall ability to act as gatekeepers whose mandate is to protect the welfare of humans participating in health research could be compromised. On the other hand, some of the newer committees have a very small volume of work. This may be a reflection of the centres being relatively new, or the low calibre of their scientists failing to attract scientific work. These committees indeed have an opportunity to build up their systems as research output increases.

The fact that there are still some ERCs operating without SOPs in place is a serious cause for concern. This could be attributed partly to the insufficiency of training provided to committee members, and partly to the meagre resources available to the committees. Since the majority of committee members have other major duties apart from sitting on the committees, the need to take time off from their employment to undergo training could be a limiting factor. It is therefore imperative that appropriate training programs that do not extensively

disrupt the normal core duties of the members be developed and made easily accessible.

All the surveyed committees relied on paper-based data management and archiving systems, which could compromise the ability of the committees to effectively follow up and monitor approved studies. In addition, the storage of ERCs' documents in various offices which are not specifically set aside for the committees potentially compromises the privacy and confidentiality of their work. We are pleased to report that we included procurement of software for the committees and training of the administrators in our capacity building activities. The software provides an efficient data filing system that facilitates follow-ups and monitoring of approved protocols while preventing unauthorized access to ERCs' data. Moreover, technical support is available in case any of the centres need support or training in this regard.

The limited ability of ERCs to provide oversight of approved studies negates the whole objective of protection of research participants. It should be mentioned that harm to participants could happen intentionally and/or inadvertently, hence the need to continue working with the researchers during the implementation of protocols. Thus, if ERCs in Africa are to be gatekeepers for health research, efforts should be made to ensure that capacity to monitor research activities is maximised. Given the relatively weak (or totally absent in some cases) regulatory authority capability in African countries, it is important that ethics committees enhance their oversight roles to ensure participant protection.

Training of committee members emerged as one of the greatest needs of African ERCs. Whereas training on joining the ERC is necessary to acquaint new members with the ethical review process, continuing training is critical to keep the committee members abreast of new developments in the health sector that could change the nature of ethical issues or lead to new ethical issues cropping up. In the ongoing training activities, the committees are also being supported to develop/improve their operating procedures; an effort is ongoing to ensure harmonization of the key SOPs that would eventually allow for a certification or indeed an accreditation programme. The authors recognise the importance of providing the basic requirements in resources and training, before developing a standard for certification and/or accreditation: it is envisaged that a stringent evaluation will be undertaken to review the operations, processes and documentation of a committee against the standard being developed before provision of the certification.

It is clear that for excellence in ethics review processes to be achieved in Africa much more investment will be required. Career structures need to be changed so that

research ethics is recognised as a career that young Africans may be willing to take professionally. Revenue and support for ERCs need to be addressed so they meet the real operational demands that satisfy international standards. Further, biomedical research stakeholders, including funding organisations, need to recognise that parallel and equal investment is necessary for ethics committees that support the research environment in Africa. In other words, ethical review of health research should be considered to be as important as the actual health research, and should be equally funded.

Capacity building efforts based on identified needs

The authors are contributing towards alleviating the prevailing situation through four approaches. Firstly, short-term (one week long) training workshops on basic health research ethics (HRE) covering various training needs revealed by the survey are being organised. In order to ensure that the majority of the ERCs across Africa have an opportunity to undergo the training, a total of eight workshops on HRE, two of which will be in French for the benefit of francophone countries, will be organized over a period of four years. In addition, five workshops on advanced HRE will be organized over the four-year project. As part of the effort to establish minimum acceptable ethical review standards across Africa, a workshop on harmonization of SOPs will be organized at a point when all the ERCs participating in the project have at least established functional SOPs. Members of the committees will be offered scholarships to attend the workshops.

Secondly, capacity strengthening subgrants will be provided to a cohort of 21 ERCs, which will be followed for a period of four years. The subgrants will go a long way in addressing financial needs as the committees build up their capacity. The subgrants are to be spent mainly on establishing offices for the ERCs, upgrading data management and archiving systems from paper-based to electronic systems, developing and/or improving SOPs, monitoring approved projects, and in-house training of committee members.

Thirdly, an online health research ethics discussion forum that is aimed at promoting debate and sharing of ideas in the public domain has been launched.⁹ The HRE

forum enables stakeholders to share ideas on ethical challenges and dilemmas encountered in the field. Real life case studies have been made available on the forum for discussion. In addition, participants can present ethical challenges or dilemmas they may have encountered themselves in the course of their work. In an effort to break language barriers between anglophone and francophone ERCs in Africa, a Sub-Hub¹⁰ was established at Yaoundé, Cameroon, to coordinate the activities of the online discussion forum. To date, 442 participants have registered and 167 responses have been posted online by participants.

Finally, web based learning opportunities have been created on the AMANET (African Malaria Network Trust) website.¹¹ The web based Basic Health Research Ethics (BHRE) course has been highly successful with over 140 candidates having successfully completed the course and been awarded certificates. The French version of the BHRE course has been developed and piloted and will be made freely available online. In addition, two other web based courses, an Advanced Health Research Ethics (AHRE) course and a Good Clinical Practice (GCP) course, are being developed and will also be made freely available on our website in due course.

Limitations of the study

It is not known how many ERCs exist in Africa – we are not aware of any published data suggesting the total number, or of any database of all ERCs' contact details. It was therefore not possible for the survey to target all ERCs in Africa. Instead, only those ERCs for which we had contact details could be targeted. Consequently, it is not possible to determine what proportion of African ERCs the surveyed sample represents. However, in terms

of the online discussion forum, called the 'Ask the Expert/Ethicist' activity, enables participants to post any questions regarding ethical challenges and/or dilemmas they encounter in their local settings. After the interactive discussions, two expert opinions are sought from a pool of appropriate experts/ethicists before concluding remarks are prepared in English and French by the Yaoundé Sub-Hub, Cameroon.

¹⁰ The Yaoundé Sub-Hub is a coordinating centre that was set up in Yaoundé, Cameroon, in order to ensure that Ethics Review Committees in anglophone and francophone countries benefit from the AMANET capacity building activities. The Sub-Hub, which is headed by a bilingual ethicist, reviews responses posted on the HRE Discussion Forum and prepares concluding remarks, in English and French, taking into account the views of the various participants. The Sub-Hub also does translations from English to French and vice versa for AMANET, and is involved in running HRE training workshops in French.

¹¹ The AMANET web site is available at: <http://www.amanet-trust.org>

⁹ The AMANET (African Malaria Network Trust) Health Research Ethics (HRE) Discussion Forum is aimed at promoting debate and discussions on ethical challenges and dilemmas encountered in the field of health research. Real life case studies are made available online (<http://www.amanet-trust.org/discuss/>) and participants share their views and experiences by posting their comments online. A component

of the number of committees and countries covered, the current survey is arguably the most extensive conducted in Africa to date.

CONCLUSION

Although there is awareness regarding the importance and role of ERCs across Africa, as reflected by the presence of such committees in various African countries, there is a need to ensure that the committees are effective in carrying out their mandate. Ethics review committees have to operate effectively, transparently and independently before they can be able to strive towards self-reliance mainly through levies the committees could charge for ethical review and oversight of health research. The study showed that the ethical review process in Africa faces challenges in terms of inadequacy of resources, inadequate training of members, dependency on paper-based data management systems, and lack of or outdated SOPs.

In an effort to ensure that the needs assessment survey does not merely describe the existing gaps and weaknesses of ERCs across Africa, the authors are implementing an intervention that is aimed at addressing the needs identified by the survey. Ethics review committees in the current capacity building project will be given subgrants and then followed up for a period of four years to ensure that proposed objectives are achieved. It is hoped that the capacity building activities will contribute towards enhancing the competence of ethical review in Africa to a level that could facilitate a move towards certification

and/or accreditation of ERCs, which could help to ensure certain minimum standards. It is also hoped that other stakeholders in the health sector, such as academic institutions, policy makers in ministries of health, pharmaceutical companies, philanthropic funding organizations and not-for-profit organizations will intensify their efforts aimed at strengthening the mechanisms for protecting research participants in general and those in resource-constrained settings in particular.

BIOGRAPHY

Aceme Nyika, PhD, MPH, is currently the African Malaria Network Trust (AMANET) Ethics Coordinator. **Wenceslaus Kilama**, PhD, is currently the Managing Trustee of the African Malaria Network Trust (AMANET), which he founded in 2002. He was Director-General of Tanzania's National Institute for Medical Research for 17 years and previously Professor in the Faculty of Medicine, University of Dar-es-Salaam (1970–1980). His keen interest in Ethics has led to his involvement in capacity building activities in health research ethics across sub-Saharan Africa. **Godfrey B. Tangwa**, PhD, is a bioethicist with a background in philosophy. He is professor of philosophy and current head of department at the University of Yaounde 1 in Cameroon. He is a member of several ethics review committees in Cameroon and abroad. **Roma Chilengi**, BSc, MBChB, DHTM, MSc- Epidemiology, CCRA, is currently the African Malaria Network Trust (AMANET) Clinical Trials Coordinator. He is a physician by background and an Epidemiologist with training in Clinical Research and Product Development. He has extensive experience in implementing clinical trials of anti malarial drugs, training in research methodologies, ethics and Good Clinical Practice (GCP). **Paulina Onvomaha Tindana**, BA, MHSc (Bioethics), Navrongo Health Research Centre, Ghana. Paulina is a Bioethicist by training and a senior research officer. She serves as a bioethicist on the Ethical, Social and Cultural (ESC) Advisory Service team of the Grand Challenges in Global Health Program.