

Strengthening research ethics oversight in Africa: The Kenyan example

L Omutoko,¹ PhD, MSc Global Bioethics; B Amugune,² PhD, PgDip (Res. Ethics); T Nyawira,³ MSc Global Bioethics; I Inwani,⁴ MMed; C Muchoki,³ MSc; M Masika,^{5,6} MB ChB, PhD; G Omosa-Manyonyi,^{5,6} MB ChC, MSc ID; C Kamau,³ MSc; L K'Apiyo,⁷ MBA; W Jaoko,^{5,6} PhD, MSc Global Bioethics

¹ Department of Educational Management, Policy and Curriculum Studies, University of Nairobi, Kenya

² Department of Pharmacy, University of Nairobi, Kenya

³ National Commission for Science Technology and Innovation (NACOSTI), Kenya

⁴ Department of Paediatrics, Kenyatta National Hospital, Nairobi, Kenya

⁵ KAVI-Institute of Clinical Research, University of Nairobi, Kenya

⁶ Department of Medical Microbiology and Immunology, University of Nairobi, Kenya

Corresponding author: W Jaoko (wjaoko07@gmail.com)

Background. Africa has seen an increase in the number of health research projects being conducted on the continent, particularly clinical trials. Ideally, this should be accompanied by a commensurate improvement in research ethics review capacity to competently provide the much-required research ethics oversight. Unfortunately, this is not the case in many African countries, which are still grappling with weak research ethics oversight capacity, not only at national level but also at institutional level.

Objectives. To describe the proposal by Kenya's national research ethics regulatory authority, the National Commission for Science Technology and Innovation (NACOSTI), to build the capacity of its National Scientific and Ethics Committee (NSEC), tasked with providing the required research ethics oversight in the country.

Methods. This is the proposal submitted by NACOSTI to the European and Developing Countries Clinical Trials Partnership for funding of a project entitled 'Strengthening Research Ethics and Oversight in Kenya' (STReK). It describes the activities involved to strengthen the NSEC to provide the required research ethics in the country, and to build the research ethics capacity of research ethics committees (RECs) it has accredited, through training and mentorship programmes, to enable them to efficiently review research proposals.

Results. Proposed activities of the project are presented. Implementation of the activities described is ongoing.

Conclusion. Lessons learnt in this regard may be of benefit to other research ethics regulatory authorities in resource-constrained countries aiming to strengthen their research ethics oversight capacity.

S Afr J Bioethics Law 2023;16(1):e199. <https://doi.org/10.7196/SAJBL.2023.v16i1.199>

Clinical trials are crucial in the research and development of new health products, and key in the discovery of interventions for otherwise devastating diseases endemic in Africa, such as malaria, leishmaniasis, tuberculosis and trypanosomiasis. They bring with them an accompanying improvement of public health and local infrastructure, and the economic boost that results from massive research funds invested locally.^[1] The number of clinical trials taking place in Africa is still relatively low compared with other parts of the globe: although Africa represents ~15% of the world's population,^[2,3] it is estimated that only 2% of clinical trials conducted worldwide take place on the continent.^[4] There are several possible reasons for this disparity, chiefly the inadequate ethical and regulatory oversight capacity for such trials.^[5]

Despite this, Africa continues to see an upward trend in the number of clinical trials as pharmaceutical companies move their research sites to developing countries.^[6] There are many reasons for this shift: firstly, the higher cost of conducting trials in resource-rich countries is becoming prohibitive to companies driven by the desire

to make a profit for their shareholders. Secondly, Africa provides access to a population with diverse genetics, and large numbers of treatment-naïve patients. Thirdly, it is challenging to find enough trial participants in large phase-three clinical trials in resource-rich countries, making it necessary for sponsors to look for additional sites in other parts of the world.

There are two major concerns in conducting clinical trials in Africa. Firstly, many people on the continent are poor,^[7] and for them clinical trials are a way of accessing medical care. This puts them at great risk of being exploited.^[1] Secondly, the low level of education can be a barrier in obtaining informed consent. Clinical trial information is often too complex for participants to understand despite efforts by researchers to simplify the language. People in Africa are therefore easily enrolled into clinical trials on drugs and vaccines without giving serious thought to their potential risks and possible side-effects.

One way of addressing these concerns is to have robust RECs to ensure the safety of research participants by thorough review of research protocols to be certain that international research ethics

standards are met for local research projects.^[8] This is crucial in guaranteeing that researchers from resource-rich countries do not conduct research in Africa that would not be allowed by the robust research regulatory frameworks in their own countries,^[9] and would aid in preventing 'ethics dumping'.^[10,11]

The surge in the number of clinical trials being conducted in Africa has created an urgent need for competent RECs to review clinical trial proposals, and to provide ethical oversight in the conducting of these trials. Many African countries do not yet have adequate capacity to ensure that clinical trials are conducted according to internationally accepted ethics standards.^[12] Studies suggest that the challenges preventing RECs in Africa from being effective include insufficient training of members and inadequate capacity to review and monitor studies, among others.^[13] Several efforts have been made to address this deficiency and build capacity for RECs in Africa.^[14] These have resulted in programmes such as the South Africa Research Training Initiative (SARETI),^[15] Advanced Research Ethics Training in Southern Africa (ARESA),^[16] Centre for Biomedical Ethics and Culture/Kenya Medical Research Institute (CBEC-KEMRI) Bioethics Training Initiative – to name a few. In addition, REC members in Africa can access research ethics training offered through e-learning platforms such as Training Resources in Research Ethics Evaluation (TRREE),^[17] Global Health Network,^[18] Collaborative Institutional Training Initiative (CITI),^[19] the National Institutes of Health^[20] and Family Health International (FHI),^[21] among others.

Ethical oversight for the conducting of clinical trials in Kenya

NACOSTI is responsible for research ethics oversight of clinical trials in Kenya and carries this mandate via NSEC. The NSEC accredits all RECs in the country, and delegates to them the responsibility of ensuring that research involving human participants complies with national and international ethics principles. Until 2010, there were only five NSEC-accredited RECs in Kenya. Between 2000 and 2018, Kenya experienced exponential growth in newly established universities, leading to an upsurge in the number of RECs linked to these universities. By 2018 there were 25 accredited RECs, each with 10 to 15 members. This rapid increase has brought with it several challenges. Kenya currently lacks the requisite infrastructure and human resources to allow RECs to function well. The rapid surge also meant that most REC members in the country are inexperienced and lack the training and expertise required to provide research ethics oversight for studies involving human participants.

Methods

Strengthening the ethical review and oversight capacity of NSEC

NACOSTI will use a two-pronged approach to improve NSEC's ability to fulfil its mandate efficiently. Firstly, existing NSEC governance will be improved. A strategic plan will be developed, and guidelines and standard operating procedures (SOPs) implemented to standardise its operations. Secondly, the information and communication technology (ICT) infrastructure of NSEC will be improved to enable it to offer better supervision of RECs, build a network among RECs and with NSEC, and build capacity of REC members to better provide research ethics oversight for the review and approval of studies.

Development of a strategic plan, SOPs and guidelines

The strategic plan will aim to set clear strategic objectives and deliverables to streamline NSEC operations. It is also envisaged that the strategic plan will help NSEC in resource mobilisation and resource allocation efforts. It will be developed through an inclusive process involving various key stakeholders including research institutions, Kenya's Ministry of Health, and RECs. The process will involve face-to-face interviews, workshops and small group discussions. A baseline survey on the status of NSEC will be carried out to document its current operational status through a strengths, weaknesses, opportunities and threats (SWOT) analysis. A qualitative review of NSEC status will be done through key informant interviews to examine its current mandate including its functioning, organisational structure and roles of the personnel, among others. The report emanating from the review will be shared with key stakeholders for their input, and then used to develop NSEC's strategic plan with the help of a consultant. The 3-year strategic plan will be validated at a meeting with research ethics stakeholders before its launch.

A review of NSEC's SOPs will be facilitated and new SOPs developed where needed. The initial step will be to define workflows and processes in line with NSEC objectives. The review will be conducted in 3-day workshops during which existing SOPs will be examined for content and scope to determine effectiveness and gaps that may exist. In addition, implementation of the existing SOPs will be evaluated to identify areas of strength and note areas that need improvement. Critical areas lacking SOPs will be identified. Groups will then be assigned to work on reviewing the existing SOPs and to develop missing ones. This will be followed by meetings for consensus and adoption of the SOPs. The process for review and development of the SOPs and guidelines will be documented, and templates developed for adoption by both NSEC and RECs.

Improving ICT infrastructure at NSEC

The first step planned is to install an information management system (IMS) at NSEC. This will include collecting baseline data on the existing status of the ICT infrastructure to determine the gaps that exist, with a view to addressing these gaps in line with organisational objectives. Information obtained will be used to select the type of IMS to be procured and installed. The IMS will be used to update the NSEC on the operations of RECs, and for monitoring and evaluation of their performance. A database will be developed to store information from all accredited RECs. The database will contain information on the numbers and types of research proposals submitted to RECs; research titles and names of the principal investigators; categories of research (such as academic, collaborative, or clinical trials); studies reviewed; and whether approved or disapproved by each REC. In addition, NSEC will build and maintain a database of all accredited RECs, their membership, expertise and experience to facilitate networking and consultation among them. An ICT officer will be trained in the maintenance of the IMS and will then train other officers and RECs to access and use the system.

Improving the ethical review and oversight capacity of REC members

NSEC will provide standardised training and mentorship to members of newly established RECs, to improve the skills of REC members in

ethical review and oversight in health research. In addition, a regional research ethics conference will be held to enable REC members to network, form collaborations, and share best practices.

Training of REC members

STReK Project had intended to develop a research training package to be used to train members of RECs. However, a national research ethics training guide^[22] was developed by NSEC before the start of the grant. STReK Project will therefore adopt the existing training guide for use in training REC members. The guide has 14 modules: Introduction to research ethics; Ethical principles in research; Research study designs; Informed consent in research; Research involving vulnerable populations; Research integrity; Research involving animals; Community engagement in research; Emerging issues in research; Composition and functioning of RECs; Research proposal review process; Post-approval monitoring of approved protocols; Continuous quality improvement of RECs; and Institutional support of RECs.

The 3-day training workshops will be geared towards enabling REC members to review research proposals, and in particular, clinical trials, more efficiently and effectively; and to adequately monitor the studies that have been approved. Training data collected will include pre-training evaluation, post-training evaluation and course evaluation, and the feedback obtained will be used to improve subsequent trainings. With respect to the actual research ethics trainings, trainees will be identified from the newly established RECs, with facilitators being drawn from established RECs, members of NSEC and other ethicists. The facilitators will be selected based on their training and experience in research ethics.

Mentorship programme for REC members

NSEC will establish a structured mentorship programme for REC members. First, the NSEC will develop mentorship tools consisting of a mentorship guide with a mentee logbook to be used during clerkship by REC members on attachment at mentorship centres. The mentorship guide will clearly indicate the roles of the mentorship sites, the mentors and the mentees, and a process for the mentorship. Three RECs with Federal Wide Assurance (FWA) numbers granted by the Office for Human Research Protections (OHRP) for compliance with US Health and Human Services regulations for protection of human subjects, will serve as mentorship centres. These are: Kenyatta National Hospital-University of Nairobi Research and Ethics Committee (FWA 00002173); Scientific and Ethics Research Unit of Kenya Medical Research Institute (FWA 00002066); and Moi University/Moi Teaching and Referral Hospital Research Ethics Committee (FWA 00003128). These RECs will provide clerkships consisting of a practicum in three ethics review committee meetings. Prior to the review meeting sessions, mentees will be assigned mentors with whom to jointly review a protocol scheduled for discussion at the REC meeting. The protocol will be sent to the mentees in advance. In addition to this review process, mentees will observe and participate in other REC activities including but not limited to receipt of protocols; their tracking; decision-making and communication of the outcomes; appeals; reporting; and renewal of approvals. Scheduled meetings between mentors and mentees are envisaged. These meetings may be face-to-face or virtual and will be

arranged to cover specific functional tasks in the review process cycle. Periodic feedback on mentee experiences will be shared and further discussion and guidance sought on unaddressed or unclear issues. Records of all activities a mentee participates in will be captured using a mentorship logbook. Mentees will evaluate their experience using an evaluation tool, for feedback to the mentoring sites.

Research ethics conference

In the final year of this grant, STReK Project will organise a research ethics conference for the purposes of networking between RECs for purposes of benchmarking, sharing of experiences and learning. The 3-day conference will consist of plenary sessions with keynote addresses by renowned research ethics practitioners, panel discussions, posters and short oral presentations for the sharing of scholarly work and ethics review experiences.

Dissemination of results

The results of this project will be disseminated through several avenues, such as the regional research ethics conference; scientific communications; policy briefs; publications in peer-reviewed scientific journals and stakeholder forums; and also through print, social and mass media.

Discussion

This article presents a proposal by Kenya's research ethics national regulatory authority, the National Commission for Science Technology and Innovation (NACOSTI), to strengthen its National Scientific and Ethics Committee (NSEC) in providing research ethics oversight in Kenya. The proposal is already being implemented, under a project dubbed Strengthening Research Ethics Oversight in Kenya (STReK) Project. By the end of this project, it is anticipated that NSEC will have strengthened its operational systems and improved its functionality by using the developed strategic plan, SOPs and guidelines, and the improved ICT infrastructure.

A good strategic plan has great benefits for organisations. It gives them a sense of direction, increases their operational efficiency and provides them with better corporate governance.^[23] SOPs and guidelines are quality assurance tools. These concepts have largely been adopted from the industrial sector, where they are used to ensure consistent quality in manufactured products, and from the business sector. They are documents that describe in detail the steps to be followed in performing a given operation. SOPs and guidelines aim at guaranteeing that tasks are performed in the same way consistently, and at improving performance.^[24] The net effect of the strategic plan, guidelines and SOPs will be better facilitation of NSEC.

The benefits of ICT in streamlining operations in organisations cannot be underestimated. Improved ICT infrastructure by installation of an IMS will help NSEC to keep abreast of the activities of RECs and hence NSEC will be able to promptly identify any that may be needing support. It will also assist in networking all accredited RECs with the NSEC, and with each other. In addition, it is also anticipated that the improved ICT infrastructure will facilitate timely reporting from the RECs, including the status of studies they have received, those that they have reviewed and those that they have approved or rejected. Robust ICT infrastructure will also facilitate access to databases of crucial information like clinical trial registries, training

records of reviewers, and available expert reviewers across the RECs. The development of interaction between the established RECs and newly created ones will in addition lead to a more integrated and co-ordinated clinical trial environment in Kenya. The net effect of these improvements will be an NSEC enabled to perform its research ethics oversight role optimally.

A high level of responsibility is placed on REC members to protect research participants and provide oversight in the ethical conduct of research that they approve. It is not possible for REC members to do this without adequate training in research ethics.^[25] Research ethics training is therefore central to the development of competence of REC members. Mentorship provides additional benefits as new REC members learn from more experienced members. The training and mentorship of REC members through STReK Project will equip participants with the necessary skills to efficiently review clinical trial applications for sound ethical considerations, and thus be able to provide the necessary oversight for the clinical trials on behalf of the NSEC. Through the anticipated efficient review of protocols by the built capacity, the quality and reliability of data emanating from clinical trials carried out in Kenya is expected to improve immensely because of this grant. It is hypothesised that the net effect of these improvements will be a better environment for conducting clinical trials. It is anticipated that with time, probably within 3 years of the end of the grant, at least three other RECs in Kenya will be able to oversee the conduct of multinational trials to the highest international research ethical standards, and also to attain international accreditation so as to increase the local capacity to absorb such clinical trials. For sustainability, it is anticipated that even after the EDCTP funding comes to an end, the research ethics trainings will continue to be conducted to build a pool of people trained in research ethics who can be ready to serve on RECs when called upon to do so.

Lessons learned from Kenya's experience may be adopted by other resource-constrained countries in the region and in other parts of Africa, while taking into consideration research ethics regulation structures that may be country-specific.

Conclusion

This article has highlighted the potential benefits of a project funded by EDCTP aimed at strengthening research ethics in Kenya. The results of the implementation of this grant will be presented in a future article at the end of the project.

Declaration. This was not research involving human research participants and therefore did not require research ethics approval.

Acknowledgements. We wish to acknowledge the enormous support provided to STReK Project by the following people: Christine Obare (Administrative); Moses Mundia (ICT); Nancy Thairu (Finance); and Boniface Wanyama and Joan Chepleting (NSEC Secretariat).

Author contributions. All authors were involved in the preparation of this article.

Funding. The activities in this article were supported by an EDCTP Grant (CSA2017ERC-1857) which is part of the EDCTP2 programme supported by the European Union.

Conflicts of interest. None.

1. Weigmann E. The ethics of global clinical trials. *EMBO Reports* 2015;16:566-570. <https://doi.org/10.15252/embr.201540398>
2. Fekadu A, Teferra S, Hailu A, et al. International Clinical Trial Day and clinical trials in Ethiopia and Africa. *Trials* 2014;15:493. <https://doi.org/10.1186/1745-6215-15-493>
3. Livi-Bacci M. *A Concise History of World Population*. New Jersey: John Wiley & Sons, 2017.
4. Bairu M, Chin R, eds. *Global Clinical Trials Playbook: Capacity and Capability Building*. Amsterdam: Elsevier, 2012.
5. Nabyonga-Orem J, Asamani JA, Makanga M. The state of health research governance in Africa: What do we know and how can we improve? *Health Res Pol Sys* 2021;19(1):1.
6. Devasenapathy N, Singh K, Prabhakaran D. Conduct of clinical trials in developing countries: A perspective. *Curr Opin Cardiol* 2009;24(4):295-300. <https://doi.org/10.1097/HCO.0b013e32823af21b6>.
7. Castaneda Aguilar RA, Lakner C, Prydz E, et al. Estimating Global Poverty in Stata: The PovcalNet Command. Washington, DC: World Bank, 2019.
8. Kruger M, Ndebele P, Horn L, eds. *Research Ethics in Africa: A Resource for Research Ethics Committees*. Stellenbosch: Sun Media, 2014:4-10.
9. Washington HA. *Medical Apartheid*. New York: Anchor Books, 2006:392-393.
10. Schroeder D, Cook J, Hirsch F, Fenet S, Muthuswamy V. *Ethics Dumping: Case Studies from North-South Research Collaborations*. Cham, Switzerland: Springer Nature, 2020.
11. Chatfield K, Schroeder D, Guantai A, et al. Preventing ethics dumping: The challenges for Kenyan research ethics committees. *Res Ethics* 2021;17(1):23-44.
12. Benatar SR. Reflections and recommendations on research ethics in developing countries. *Soc Sci Med* 2002;54:1131-1141.
13. Silaigwane B, Wassenaar D. Biomedical research ethics committees in sub-Saharan Africa: A collective review of their structure, functioning and outcomes. *J Empir Res Human Res Ethics* 2015;10(2):169-184.
14. Mokgatla B, Ijsselmuiden C, Wassenaar D, Kasule M. Mapping research ethics committees in Africa: Evidence of the growth of ethics review of health research in Africa. *Dev World Bioethics* 2018;18:341-348.
15. Wassenaar D. South African Research Ethics Training Initiative (SARETI). *S Afr J Bioethics Law* 2011;4(2):107-108.
16. Keymanthri M, Rennie S. Advancing Research Ethics Training in Southern Africa (ARESA). *S Afr J Bioethics Law* 2011;4(2):104-105.
17. Training and Resources in Research Ethics Evaluation (TRREE). <https://elearning.trree.org/> (accessed 5 May 2023).
18. Global Health Network. Global Health Training Programme. <https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/> (accessed 5 May 2023).
19. Collaborative Institutional Training Initiative (CITI). <https://www.citiprogram.org/> (accessed 5 May 2023).
20. National Institute of Health (NIH). NIH research ethics training. <https://researchethics.od.nih.gov/> (accessed 5 May 2023).
21. Family Health International. <https://www.fhi360.org/countries/kenya> (accessed 5 May 2023).
22. National Bioethics Committee, National Commission for Science, Technology and Innovation. *Training Guide for Institutional Ethics Review Committees in Kenya*. Nairobi: NBC/NACOSTI, 2020.
23. Kabeyi MJB. Organisational strategic planning, implementation and evaluation with analysis of challenges and benefits. *Int J Applied Res* 2019;5(6):27-32.
24. Akyar I. Standard operating procedures (What are they good for?) In: Akyar I, ed. *Latest Research in Quality Control*. Turkey: IntechOpen Books, 2012:368-390.
25. Davies H, Wells F, Druml C. How can we provide effective training for research ethics committee members? A European assessment. *J Med Ethics* 2008;34:301-302. <https://doi.org/10.1136/jme.2007.021485>

Accepted 26 February 2023.