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Preventing ethics dumping: the challenges for Kenyan research ethics committees

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Abstract

Ethics dumping is the practice of undertaking research in a low- or middle-income setting which would not be permitted, or would be severely restricted, in a high-income setting. Whilst Kenya operates a sophisticated research governance system, resource constraints and the relatively low number of accredited research ethics committees limit the capacity

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for ensuring ethical compliance. As a result, Kenya has been experiencing cases of ethics dumping. This article presents 11 challenges in the context of preventing ethics dumping in Kenya, namely variations in governance standards, resistance to double ethics review, resource constraints, unresolved issues in the management of biological samples, unresolved issues in the management of primary data, unsuitable informed consent procedures, cultural insensitivity, differing standards of care, reluctance to provide feedback to research communities, power differentials which facilitate the exploitation of local researchers and lack of local relevance and/or affordability of the resultant products. A reflective approach for researchers, built around the values of fairness, respect, care and honesty, is presented as a means of taking shared responsibility for preventing ethics dumping.

Keywords
Research ethics, research governance, Kenya, ethics dumping, international research collaborations, values

Ethics dumping

International research collaborations can be highly beneficial as 'scientists have most impact when they're free to move' (Sugimoto et al., 2017: 29). Through collaborations, low- and middle-income countries (LMICs) can obtain funding, training or equipment that would otherwise not be available to them (Bradley, 2017; Macklin, 2004), whilst high-income countries (HICs) can obtain operational and/or economic advantages (Dickson, 2006; Luna, 2009; Macklin, 2004; Weigmann, 2015).

This positive picture of international research collaborations can be undermined by a practice called ethics dumping (European Commission, 2016). Ethics dumping involves the export of research which would be severely restricted or not permitted in HICs to LMICs, where ethical review processes, compliance structures and follow-up mechanisms might not be as well-resourced or supported (Novoa-Heckel et al., 2017; Schroeder et al., 2018, 2019).

Typical examples of ethics dumping in international collaborative research include a group of three US-funded clinical trials with a placebo arm conducted in India, even though a standard of care treatment was available (Srinivasan et al., 2018); research on wild-caught, non-human primates in Kenya, which would have been prohibited in the home institution of the UK investigator (Chatfield and Morton, 2018); the export and profitable commercialisation of blood samples from China to the US without local benefit sharing (Zhao and Zhang, 2018); or the undertaking of highly ethically sensitive research by an international researcher without research ethics committee (REC) approval in Liberia (Tegli, 2018).

LMIC RECs have a critical role to play in protection from ethics dumping. However, many African RECs are faced with a scarcity of resources, insufficient training of members, inadequate capacity to review and monitor approved

studies and a lack of national ethics guidelines and accreditation (Silaigwana and Wassenaar, 2015).

This paper illuminates the challenges faced by Kenyan RECs in the prevention of ethics dumping in five sections. The first section summarises the research ethics governance mechanisms available in Kenya and the following describes the methods used to write this international collaborative paper. The central, third section presents 11 challenges for RECs in the prevention of ethics dumping in Kenya. The section entitled 'Ways Forward' offers a reflective approach to assist researchers in the prevention of ethics dumping, whilst the final section concludes.

Research ethics governance in Kenya

The highest Kenyan governance authority for research is the National Commission for Science, Technology and Innovation (NaCOSTI), which 'regulate[s] and assure[s] quality in the science, technology and innovation sector. It also advise[s] the Government in matters related thereto' (NaCOSTI, 2020a: n.p.), drawing its authority from the Technology and Innovation Act 2013.

For the Kenyan authorities, 'research refers to any investigation or inquiry or interview that aims to collect data or information, academic or non-academic, that will lead to new information and/or knowledge' (NaCOSTI, 2020b: n.p.). Anybody who wants to conduct research in Kenya needs to apply for a research licence (NaCOSTI, 2020b).

In addition to providing research licences, NaCOSTI also accredits RECs, which in turn review all research that involves human participants or animals (NaCOSTI, 2017) within well-defined institutions. In Kenya, ethics approvals have to be obtained locally, whether or not studies have received approvals from non-Kenyan RECs of collaborating institutions

Currently, 30 RECs are accredited across Kenya (NaCOSTI, 2020c) in universities, hospitals and research institutes. In addition, Kenya has a national REC, which approves studies in the following cases:

- the site at which a study takes place has no accredited local REC;
- the study is deemed to be of national importance; or
- the study raises particularly sensitive ethical issues.

At first sight, Kenyan research governance structures appear to be well placed to prevent ethics dumping. For instance, there is no lack of national ethics guidelines (e.g. NCST, 2004) or accreditation systems (NaCOSTI, 2017), two elements that weaken other African systems (Silaigwana and Wassenaar, 2015). However, while governance structures in Kenya provide a robust framework, there are serious strains upon the system, especially with regard to the monitoring of research studies[1] (Wekesa, 2015).

Methods

Finding the most appropriate method to identify unresolved Kenyan challenges in the prevention of ethics dumping poses an ethical conundrum in itself. The identification of cases and causes of ethics dumping requires considerable ethics expertise and experience of international collaborative research. In Kenya, the most knowledgeable researchers for this topic would therefore be experienced Kenyan REC chairs or senior Kenyan collaborators in global research with an ethics portfolio. But these are exactly the kind of colleagues whose time is scarce, given the constraints upon African RECs (Kass et al., 2007; Nyika et al., 2009; Silaigwana and Wassenaar, 2015). If, however, the time burden was shifted to European REC chairs or senior collaborators in international research, in order to conduct interviews and focus groups in Kenya, another problem would arise. Whilst valuable time might be freed for Kenyan colleagues, the result would be yet another publication written from a European perspective. In international collaborative research, the odds in publication success are already weighted heavily in favour of HIC collaborators, a fact which is increasingly criticised (Chu et al., 2014; Smith et al., 2014).

To resolve this dilemma, representatives from various stakeholder groups came together and worked in an iterative manner, utilising workshop-based presentations, consultations, staged analysis and joint integration to achieve equitable co-production and co-authorship.[2] The approach is illustrated in Figure 1.

This paper itself therefore practices an alternative to the type of approach that sees HIC researchers travel to an LMIC to conduct qualitative research which they analyse and publish as findings 'about' Kenya. The approach can be summarised in five steps.

1. Senior Kenyan REC chairs selected real-life examples of potential ethics dumping from their areas of expertise.[3] Some examples could be stopped by the REC, some not. They then presented the identified challenges at an international, invite-only workshop on the topic of ethics dumping in Africa.
2. The workshop attendees (ethics dumping experts, senior REC chairs, representatives of vulnerable research populations, industry and funders as well as researchers) contributed further real-world experiences and commented critically on the challenges presented.
3. A recording of the event provided data for post-workshop analysis to reveal the major challenges in the prevention of ethics dumping in Kenya.
4. First-hand experiences recorded at the workshop were combined, contextualised and analysed in the light of the academic literature, especially with respect to ethics dumping.
5. This analysis was refined by the authors in an iterative manner until convergence in understanding was achieved for this publication.

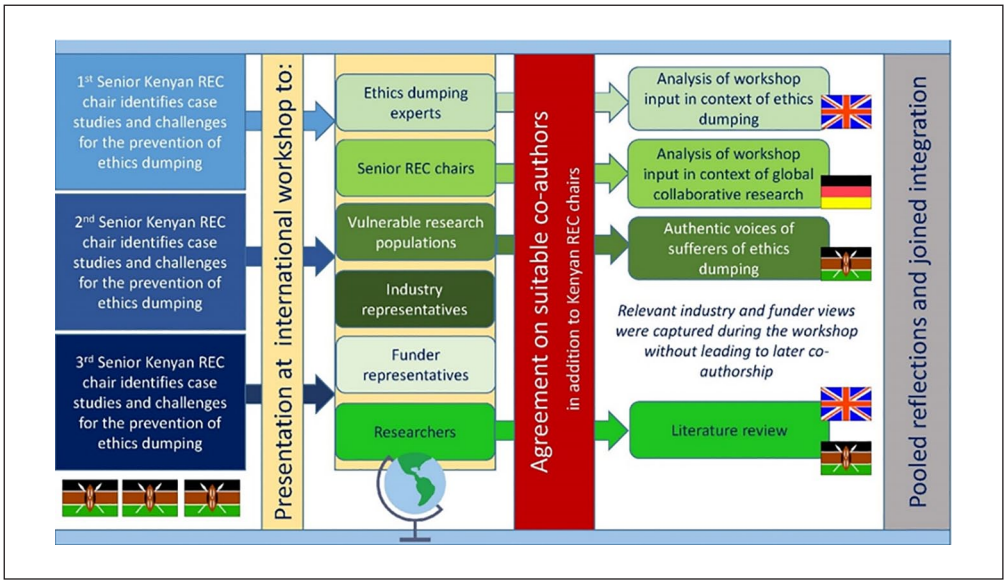

Figure 1. Co-production and co-authorship on preventing ethics dumping in Kenya.

Challenges for Kenyan RECs

The identified challenges are presented in two categories: research governance and research ethics. Governance is understood as the 'institutions and processes that determine how . . . decisions are made on issues of public concern' (Lee, 2003: 5). The conduct of research and the distribution of burdens and advantages is an issue of public concern, hence *research* governance. Research ethics is understood as the standards, principles, values, virtues, ideals and/or rules that ensure the *moral* conduct of research (Schroeder et al., 2019).

While there are undoubtedly overlaps between research governance and research ethics (Ashcroft, 2003), it is helpful to differentiate between challenges for the regulation of a research project and challenges for its adherence to *ethical* obligations (Iphofen, 2017). This differentiation helps to identify systemic weaknesses and also to identify which measures could be taken to address them. Table 1 summarises the primary challenges for the prevention of ethics dumping in Kenya in the context of research governance and/or research ethics.

Research governance challenges

Variations in governance standards and procedures

A fundamental challenge for collaborative research between HIC and LMIC partners arises from the lack of equivalence in standards between countries. This can act as an incentive for researchers who wish to conduct activities that would not be

Table 1. Primary challenges for Kenyan RECs in their strategies to prevent ethics dumping.

Challenges for research governance	Challenges for research ethics
• Variations in governance standards and procedures between countries	• Power differentials and the exploitation of local researchers
• Resistance to double ethics review	• Lack of local relevance and/or affordability of resultant products
• Resource constraints on RECs	• Unsuitable informed consent procedures
• Unresolved issues in the management of biological samples	• Inadequate cultural sensitivity
• Unresolved issues in the management of primary data	• Lack of feedback/dissemination to the LMIC community
	• Standards of usual care differ between partners

Note: LMIC: low- and middle-income country; REC: research ethics committee.

permitted in their own country to seek opportunities abroad. For instance, in line with Article 20 of the *Declaration of Helsinki* (World Medical Association, 2013), research with vulnerable participants is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out with a non-vulnerable group. Hence, access to vulnerable populations is restricted.

Most HICs have sophisticated procedures in place to protect vulnerable research participants. However, in Kenya, such systems are not as robust or wide-reaching as necessary and, in some specific instances, they are weak. For example, there is no specific regulation protecting prisoners from exploitation in research; on the contrary, they are an easily accessible population. One real-life REC decision which prevented potentially harmful research on Kenyan prisoners involved research that was devised for the sole benefit of an HIC country's military personnel. Whilst this study was prevented by a vigilant Kenyan REC, the lack of protective regulation for prisoners remains a challenge to safeguarding them from exploitation in research. For instance, when a proposal for international collaborative research is rejected by one Kenyan REC, applicants have been known to 'shop around' in an attempt to find another REC that will approve their study.

Resistance to double ethics review

All research involving humans or animals in Kenya must be approved by an accredited Kenyan REC before it can proceed, even if the study has been approved by a REC elsewhere. Proposals are therefore commonly subjected to review by RECs in the different countries involved (*double* ethics review), each with its own processes and requirements. In addition, collaborative studies utilizing more than one local (Kenyan) site for their study are expected to obtain ethics approvals from all the RECs overseeing research in the respective sites. This process can be

expensive and time-consuming if not appropriately handled and facilitated; it can lead to delays in timely implementation of research studies, hence attracting both internal and external resistance. Resistance to multiple ethics review remains a weak link in preventing ethics dumping in Kenya due to differentials in the technical capacity, experience and resources available to the accredited RECs.

Kenyan RECs must ensure that international researchers comply with Kenyan laws and ethics requirements. However, the Kenyan REC authors have experienced some researchers being reluctant to provide necessary details about the project to the Kenyan RECs, meaning they are not able to conduct a full review. For instance, one HIC research team refused to provide a breakdown of costs, even though budgets are often a good indicator of potential inequities.[4]

Some HIC researchers have insisted that the Kenyan REC should accept the HIC ethics approvals they bring with them. While this disrespectful approach to Kenyan research governance requirements may be rare, proposals are often submitted at short notice, in the wrong format (often unaltered from a previous application to the HIC REC), with pressure applied on the Kenyan REC to grant approval in a hurry. The Kenyan REC authors of this paper have reported personal experiences of HIC researchers walking into their offices unexpectedly to demand swift approval and complaining if this is not forthcoming.[5] In some cases, research funds had already been spent in the set-up phase with HIC teams already relocated to Kenya. This approach to obtaining ethics approval is likely to overburden RECs that are already working at full capacity and could compromise the quality of review. More worryingly, retrospective approval is sometimes sought at the point of the release of findings in order to satisfy publication requirements (Tegli, 2018).

Resource constraints on RECs

While there are currently 30 accredited RECs in Kenya, these RECs are overburdened with heavy workloads, an experience they share with other RECs on the African continent (Kass et al., 2007; Nyika et al., 2009; Silaigwana and Wassenaar, 2015). These time and resource constraints often mean that ethics approval is delayed, and follow-up or monitoring of research studies cannot be undertaken. Some studies, especially clinical trials, have built-in monitoring procedures that are funded as part of the trial to ensure full compliance with the study operating procedures and protocol. However, many studies, especially of a non-medical nature and with smaller budgets, do not have the resources or systems in place for ongoing evaluation and monitoring.

Unresolved issues in the management of biological samples

A long-standing challenge in biomedical research concerns the ethical management of biological samples, including matters pertaining to their collection, storage,

reuse, disposal and export.[6] While these governance issues are not limited to international collaborative research (Tindana et al., 2014), certain ventures between HICs and LMICs have highlighted the acute risks for exploitation of research participants in LMICs by HIC collaborators. For instance, Zhao and Zhang (2018) describe a controversial case where the export of thousands of human genetic samples gathered from China without adequate informed consent led to significant commercial benefits for a US company.

Biological samples collected for research in Kenya include blood, blood products, genital secretions, biopsies and genetic and pathological materials. In the past, when Kenyan laboratories were not well-equipped, samples were routinely taken abroad for storage and analysis (Cook Lucas et al., 2013). Kenya now has a growing number of facilities for sample storage and analysis, and many of these developments have been supported through collaboration with HIC partners (Sathar and Dhai, 2012). Nevertheless, while strengthened capacity of LMIC research institutions can enhance local control of samples, Tindana et al. (2014) observe that no level of local capacity can completely eliminate sample export.

Unresolved issues in the management of primary data

Primary data are collected first-hand by researchers in surveys, interviews, observations, measurements, experiments or clinical tests. Such data are often exported by HIC researchers, giving Kenyan RECs no influence over their use beyond the original purpose stated in the ethics approval.

Not only can such data be misused (e.g. falling outside of the original informed consent and approval parameters), but this inequitable approach to data management also creates disadvantages for local researchers and communities. Kenyan researchers lose the ability to benefit from the use of the data. The management of primary data is a critical issue in HIC-LMIC research collaborations (Parker et al., 2009) because primary data can be a considerable scientific or commercial asset for the owner of the data. For instance, data can be treated as a commodity, with access rights being sold for many years after the original data collection. HIC researchers may continue to publish papers based on secondary findings derived from data collected years earlier without seeking host country REC approval for this additional use.

Kenyan RECs are therefore trying to ensure that, wherever possible, primary data remains in Kenya so that their subsequent use can benefit Kenyan research teams and communities. This requires the provision of specific information and agreements about data ownership, data management and access procedures, prior to research approval. This complex task is not always straightforward for under-resourced and overburdened RECs negotiating with well-resourced HIC researchers and institutions.

Research ethics challenges

Power differentials and the exploitation of local researchers

There can be a significant imbalance between collaborating HIC and LMIC partners concerning duties, salaries, data ownership, publications and intellectual property sharing. For instance, local researchers can be deprived of leadership or strategic roles and involved only in data collection (Tickle, 2015). As Francisca Mutapi (2019: 567) explains:

> Inequitable partnerships that task African scientists as data gatherers for Western research agendas are unlikely to make a difference to the African health problems that really matter. 'Safari science' is ineffective.

Inequities in role distributions are often the result of major power differentials between HIC and LMIC researchers and institutions. Such power differentials can start early with the setting of research agendas and funding application. 'I have sat through panels reviewing funding applications on global-health or medical research in Africa that did not include anyone from an affected country' (Mutapi, 2019: 567).

Issues emerging from the workshop included concerns about financial imbalances. Salaries that are funded by external grants can create problems. In some cases, LMIC partners are seriously underpaid (taking purchasing power parity into account), while in others they are considerably overpaid for their roles. The former leads to exploitation, the latter to conflicts of interest. Generally, HIC partners are far better resourced, which can lead to a 'big brother' attitude, where the HIC partners 'command' and LMIC partners must 'do' if they want any involvement at all.

Whilst Kenyan RECs can decide not to approve studies unless a reasonable amount of participation by local researchers is specified, it is difficult for institutions to monitor what happens when the research study commences. What HIC researchers agree to do when obtaining ethics approval does not necessarily translate into equitable research practice. According to real-life examples contributed by the Kenyan REC authors, it is still the case that findings based on Kenyan samples and Kenyan primary data are published by researchers from HIC institutions without any participation from the Kenyan researchers involved (see also Smith et al., 2014).

Lack of local relevance and/or affordability of resultant products

It is a long-standing ethical requirement that research with vulnerable populations, which includes research in resource-poor settings such as Kenya, must have local relevance. As noted earlier, Article 20 of the *Declaration of Helsinki* (World Medical Association, 2013) states that 'medical research with a vulnerable group

is only justified if the research is responsive to the health needs or priorities of this group'. An ethics-dumping case in Western Africa showed that this requirement is not always respected (Tangwa et al., 2018).

Yet, even if research that involves vulnerable populations or their biological samples is locally relevant, the benefits from any studies might not be reasonably available[7] locally. For instance, Indonesian avian flu samples were used in the production of vaccines, which were then not reasonably available in Indonesia (Cook Lucas et al., 2013).

In general, there are no priority lists for 'most needed' research in Kenya, only indications in some areas, such as HIV/AIDS prevention and treatment. It therefore falls to RECs to ask on a case-by-case basis whether the research has any local relevance and, if not, why conduct the research in Kenya?

RECs may come to the conclusion (as in the example regarding Kenyan prisoners) that local relevance is not evident. Or they may come to the conclusion that the research is highly relevant to Kenya, but that Kenyans are unlikely to be able to afford/access any of the outcomes, representing a serious problem in international collaborative research (Schroeder and Gefenas, 2012), to which Kenyan RECs alone cannot supply a solution.

Unsuitable informed consent procedures

It is essential for fully informed consent that research participants understand what they are agreeing to, but in international collaborative research there can be complex factors to consider.

Firstly, a basic challenge for all researchers is that the language of academic and scientific research is not universal or common, and understanding it may require a high level of literacy. Hence, researchers must find easier and more understandable ways to communicate with all types of participants before requesting their consent. For researchers in HICs, the provision of participant information often involves a detailed written explanation of particular aspects of the study and how it might impact upon the participants. This can result in a comprehensive document that is presented to potential participants for consideration. Obviously, this is a major challenge for people who have low literacy levels and, when translated into local languages in host countries, a document can also become a lot longer. In this context, most participants will just skim through or skip pages and place their trust in the researchers. A sex worker research participant in Nairobi makes this point clearly:

> Informed consent documents may be written in simple language and translated but not all sex-workers can read. Anyway, we often do not read the information sheet. People often participate for the money without considering the long-term effects. We need you to tell us everything in black and white. Just tell us, just be honest. Even if there is no prospect of benefit, tell me so I can make a decision. (Chatfield et al. 2016: 9)

A further consideration for the consent process is whether the researchers know how to approach a specific community. In some Kenyan circumstances, the chief or community elders perform a cultural role as gatekeepers and must be approached for community assent for the research to take place (although this does not negate the need for subsequent individual consent from participants).[8]

Inadequate cultural sensitivity

Sensitivity to cultural perspectives and practices is necessary for appropriate informed consent, as in the case of community assent.

In some cultures, it is most uncommon for people to say *no* directly, even when they oppose a proposal. Additionally, in the Kenyan medical context, there is often a paternalistic power imbalance, replicated in research, so that potential participants may not feel empowered to ask questions (Knight et al., 2018). These customs have obvious implications for informed consent procedures in international collaborative research. Researchers from HICs who are accustomed to highly literate research participants, who actively engage with the purpose of a study and its potential risks, might easily take disempowered acquiescence for authentic consent. The cultural sensitivity required in such relationships needs to be developed over time in long-standing relationships with local collaborators rather than as part of 'helicopter' or 'safari' research.

A lack of cultural sensitivity can also lead to misunderstandings. For example, in some cultures, blood is linked to the soul and spirit, and when blood is donated, it is viewed as giving part of the soul or spirit to another person. In some sub-Saharan African settings there may be a perception that blood could be used for rituals or witchcraft (Grietens et al., 2014). At the workshop, participants discussed historical instances where a whole community in Kenya refused to take part in a research study when they saw the caduceus[9] symbols on the clothes and equipment of the medical staff. In their culture, the snake symbolises the Devil and they believed that blood was being collected by devil worshippers.

When blood is taken, donors need to understand precisely why it is being taken, what it will be used for, how it will be stored and what will happen to it after the research is completed. As one Nairobi sex worker representative commented:

> We know that the samples that are collected from us are sometimes sent to other countries. What happens to them? In my culture, if blood is taken, it must come back to me and I bury it. If you do not bring it back, then you must tell me where it goes. We need to know what happens to left-overs and we are keen to benefit from the use of samples. (Chatfield et al., 2016: 11)

It is almost impossible for HIC partners to know the cultural background and sensitivities of communities well enough to avoid any distress, confusion or misunderstandings. Some instances, such as that involving the caduceus symbol, might

not be averted by a local REC either, if REC members have first-hand experience of the community. Only when communities themselves are given a chance to contribute to the design and management of each study that seeks their participation can such challenges be overcome.

Lack of feedback/study results dissemination to the LMIC community

Feedback of research findings to participants is the most basic aspect of benefit-sharing practice in research (Schroeder and Cook Lucas, 2013) as required by the *Declaration of Helsinki* (Article 26). Local dissemination of relevant findings is essential, whether they are positive or negative. Participants have a right to know what they have contributed to and to share in any resulting benefits. A Nairobi sex worker research participant commented:

> We need feedback to the community from the research in simple and non-scientific language. Some results have been fed back to us in the past but I did not know what they meant. Do not give us results in scientific language. It puts us at risk if we do not understand the results. Like one study on a treatment for HIV, some sex workers were confused and interpreted their treatment as a vaccine for HIV that led them to believe they cannot contract infection and hence no need to use protection. We may not understand all of the results – just give them to us in a way we can understand. Come back with the results and tell us how we can make our lives better. (Chatfield et al., 2016: 10)

In the experience of the three Kenyan REC authors, requirements for dissemination and feedback are often ignored by HIC researchers in practice, even though plans for such feedback formed part of the ethical approval for the study.

Standard of usual care differs between partners

Researchers and RECs can be faced with dilemmas when the standard of care differs between collaborating partners engaged in controlled clinical trials (Lavery et al., 2007; Hawkins and Emanuel, 2008). Council for International Organizations of Medical Sciences (CIOMS) (2016) *International Ethical Guidelines for Health-Related Research Involving Humans* state that, where possible, the control group should be provided with an established effective intervention. Likewise, the *Declaration of Helsinki* requires 'the best proven intervention(s)' (Article 33). In this way, no clinical trial participant is denied existing treatment and new interventions are tested against established alternatives (comparative effectiveness trials). As well as being considered more ethical, this approach is also considered to be pragmatic and hence more likely to have real-world value. However, the established interventions that are part of usual care for people in HICs may be

unaffordable or inaccessible for many of those in LMIC settings. In such situations, the research sponsors, researchers and RECs must consider whether those in the control group should be provided with the recognised level of usual care, even if that might normally be unaffordable or unavailable to them or whether to replicate the real-world LMIC situation (no care or inferior care). The former choice will inevitably raise further concerns about what happens when the trial ends, but the latter option is a clear case of ethics dumping (Srinivasan et al., 2017).

Ways Forward?

The research governance and research ethics challenges that have been identified earlier are not exclusive to global collaborative ventures in Kenya (Hawkins et al., 2008; Lavery et al., 2007). Ethics dumping can occur in any resource-poor setting (Schroeder et al., 2018, 2019). At the same time, LMIC researchers can also exploit their research colleagues, research participants or other research resources. One should not surmise from the preceding text that HIC researchers regularly exploit Kenyan communities and researchers and that Kenyan RECs are their powerless victims. Indeed, the 30 legally mandated Kenyan RECs have significant powers to prevent exploitation from either HIC or LMIC researchers. Nevertheless, the earlier examples highlight the real-life, ongoing challenges in the prevention of ethics dumping in international collaborative research as experienced by the five Kenyan authors of this paper and supported by the academic literature.

The identified challenges related to *research governance* are primarily associated with a need for more resources and tighter legal and regulatory systems. Both are beyond the immediate control of most LMIC RECs. While the existence of a legal and institutional policy framework is evidence of Kenya's intent to regulate research, its success depends largely on human and financial capital. Such capacity is still a major challenge (Wekesa, 2015).

In many respects, the *research ethics* challenges and concerns identified for Kenya echo what has been observed more widely across LMICs (Hawkins and Emanuel, 2008; Lavery et al., 2007). For instance, Joseph et al. (2016) undertook a systematic review of stakeholder views on paediatric clinical trials in LMICs. Looking at 39 studies across 22 countries, they identified major areas of concern that mirror many of the aforementioned challenges for research ethics in Kenya. These included:

- the poverty and vulnerability of potential participants in LMICs;
- the power differentials that exist between researchers and participants;
- the need to translate research into the local context taking account of cultural beliefs and ethical pluralism; and
- the need for a fair distribution of benefits.

Given the limitations for research governance and the seemingly ubiquitous challenges for research ethics in LMICs, the question arises as to *what precisely can be done to support Kenyan RECs in their strategies to prevent ethics dumping?* As a possible way forward, we suggest an approach that utilises a new ethical research framework, based upon the four values of fairness, respect, care and honesty.

A values-based approach to equitable collaborative research

To counter ethics dumping, the European Commission funded the development of a research ethics code specifically designed for this purpose. The *Global Code of Conduct for Research in Resource-Poor Settings* (Trust, 2018) has been a mandatory reference document for European Union research funding since mid-2018 (Nordling, 2018). It has also been adopted by other institutions (Mayo, 2019). The Code was co-created by a global ethics and science consortium with considerable representation from vulnerable research populations, a majority of LMIC task leaders and a majority of women leaders (Schroeder et al., 2019). It showed that the values of fairness, respect, care and honesty are violated when ethics dumping occurs, leading to a loss of trust in researchers or even research itself (Schroeder et al., 2019).

Given that trustworthiness is vital for equitable research collaborations (Tindana et al., 2014, 2019), applying the four-values approach is one way forward to address ethics dumping (Schroeder et al., 2019). Summarised descriptions of the meanings of the four values are shown in Table 2. When used as a tool for reflection, especially by researchers, they can indicate how to avoid ethics dumping.

Using this values framework, the challenges for Kenyan RECs in their efforts to prevent ethical dumping can be examined further. Table 3 maps the primary challenges from Table 1 onto the values of fairness, respect, care and honesty.

Table 3 reveals how the identified challenges can be viewed as values-related matters. Values emphasise the relationships between actors and their actions. They motivate and engage people to discharge obligations or duties at a personal level (Cook et al., 2019). The influence of personal values upon behaviour has become a subject of extensive research in the social sciences and in psychology, with just about every area of life being examined through the lens of personal values (Schroeder et al., 2019). Furthermore, people are much more contented and productive when their own values are aligned with their professional or organisational values (Posner, 2010). When researchers work with reflective awareness and from a four-values perspective, they can more easily appreciate the challenges that face Kenyan RECs regarding international collaborative research. Thus, they will be better placed and, hopefully, better motivated, to prevent ethics dumping themselves rather than relying on Kenyan RECs to stop them.

Table 2. Four values that underpin ethical research (Schroeder et al., 2019).

Fairness	Respect
Fairness can have a number of interpretations (Pogge, 2006) but the most relevant in the context of ethics dumping is *fairness in exchange*. Is the balance of benefits and burdens equitably distributed?	People's customs and cultures may be different. Researchers must ensure that their own behaviour does not cause offence. They may also need to accept a way of approaching a matter that they personally disagree with.
Care	**Honesty**
Researchers should demonstrate care by taking responsibility for the welfare of those who contribute to their research or might suffer as a result of it. This will entail the tailoring of procedures, such as informed consent, to meet local requirements (language, literacy etc.). Care also requires that time and effort is invested to achieve quality research.	Researchers should be truthful about all aspects of their work and strive for transparency in their activities. This includes not omitting important information. The value of honesty also links research ethics with research integrity, which includes issues such as credit for contributions, manipulation of data, or misappropriation of research funds.

Table 3. Primary challenges for Kenyan RECs mapped against the four values.

Fairness	Respect
• Variations in governance standards and procedures between countries • Power differentials and the exploitation of local researchers • Lack of local relevance and/or affordability of resultant products • Resource constraints on RECs	• Resistance to double ethics review • Inadequate cultural sensitivity
Care	**Honesty**
• Standards of usual care differ between partners • Lack of feedback/dissemination to the LMIC community • Unsuitable informed consent procedures	• Unresolved issues in the management of biological samples • Unresolved issues in the management of primary data

Note: LMIC: low- and middle-income countries; REC: research ethics committee.

Implementing the values of fairness, respect, care and honesty

Local RECs have a crucial role in highlighting potentially exploitative activities, but there is much more that can be done by researchers to relieve the burden upon RECs. When research proposals are imbued with fairness, respect, care and honesty, the workload on RECs can be reduced, as measures for preventing ethics dumping are already built into the research.

Community engagement. The most direct and effective way to find out what is considered fair and respectful in research is simply to ask those who will be involved or affected. This demonstrates care from the outset. There is growing recognition of the potential benefits of community engagement in international research settings. Joseph et al. (2016) concluded that effective community engagement holds the key to addressing concerns for research ethics, offering a means to improve equity for vulnerable populations/participants in LMICs. Community engagement is especially beneficial in the context of wide differentials between the researchers and participant communities in terms of their social and cultural norms, values, goals, resources and levels of technological understanding (Kamuya et al., 2013). Hence, community engagement is becoming an increasingly common feature of international collaborative research in LMICs, and numerous methods of engagement are employed, commonly involving interaction with representatives of communities (Tindana et al., 2015).

Community engagement is characteristically portrayed as an effective means of minimising the risks of exploitation and ensuring fairness in the distribution of research benefits in LMICs (Chantler et al., 2013). In international collaborative research, community engagement may also be employed to ensure that the research is relevant to local health needs (fairness), to advise on matters of cultural sensitivity (respect) and to ensure appropriate consent procedures (care). Strategies that have been successful for informing a community include meetings, gatherings and seminars with the sole purpose of sharing information about potential studies (Chatfield et al., 2018).

Fairness. Fairness is evident when local relevance has been clearly determined, but fairness takes many forms; it is also important that post-study access is negotiated prior to studies, so that products developed with Kenyan participants and resources are available in Kenya. Products should be available (marketed in the country), accessible (marketed in enough outlets) and affordable. Fairness is also realised through the equitable distribution of significant tasks in the research project. It may be difficult to achieve equitable scientific partnerships in situations where there are great disparities in resources and capacity, but this is all the more reason to strive for evidence of capacity building and thus create the conditions for equal partnerships in the future (Parker and Kwiatkowski, 2016).

Respect and care. Recruiting and training local research assistants and research educators – with appropriate remuneration – demonstrates care, as they are able to inform other community members in such a way that the risks and benefits of a study are well understood (Tukai, 2017). Effective examples of such practice have been documented, for instance by Kamuya et al. (2013) and Chantler et al. (2013).

Honesty. Our five Kenyan authors have recounted several personal experiences of researchers who have not acted as promised; for example, who ignored requirements for dissemination and feedback to the host community or who failed to include local researchers as authors of publications. A lack of honesty is also exhibited when information is withheld or transparency is absent. This is an ongoing challenge for RECs when reviewing plans for the management of primary data or biological samples. Kenyan RECs have the authority to make specific demands regarding the management of biological samples that may be lacking in many other African countries (de Vries et al., 2017). However, absolute transparency and honesty is required for decision-making regarding biological sample management, and sometimes this is not overt in REC applications.

The experiences upon which this paper is based stem largely from biomedical studies, yet, some ethics risks can be greater in social science studies. For instance, social science research participants might incriminate themselves (e.g. sex work is illegal in Kenya) or may experience significant psychological harm (e.g. if interviewed just after a health emergency) without appropriate ethical oversight (Tegli, 2018). A values-based approach can also help social science researchers, both in support of their intentions to build trustworthy relationships and in explaining their methods to RECs using a framework of what is fair, respectful, caring and honest.

Conclusion

Kenya operates a sophisticated research governance system when compared to many other African countries, yet it is still prone to ethics-dumping attempts. This is, in no small part, facilitated by local resource constraints and an insufficient number of accredited RECs. Ethics-dumping attempts are enabled both by variations in governance standards between HICs and LMICs and by the leveraging of power differentials between HIC and LMIC research teams. To reduce the burden on Kenyan RECs, HIC researchers can adopt a reflective approach based upon the values of fairness, respect, care and honesty to help increase trustworthiness in research and reduce the risk of ethics dumping.

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Notes

1. Challenges in the ethical monitoring of research are not a phenomenon restricted to LMICs (Davis, 2018). In HICs, some funders (such as the European Commission) take on part of the ethical monitoring of research studies themselves (through ethics checks and ethics auditing undertaken during the lifetime of a study, with the potential to block grant payments for non-compliance). In other cases, frameworks are set centrally (e.g. the UK Policy Framework for Health and Social Care Research) with responsibility devolved to research institutions (e.g. universities) to ensure effective monitoring of their employees' research conduct.
2. In this paper, 'REC authors' indicates three Kenyan REC chairs, one European REC chair, one UK REC vice-chair, and one member of several RECs. 'Kenyan REC authors', then refers to the three Kenyan REC chairs.
3. While the challenges described in the paper reflect actual events, no information is revealed to identify the related studies, or which author experienced the events.
4. For example, if costs for exporting samples are included in the budget, the Kenyan REC would request information on why Kenyan samples cannot be handled in-country. Costs can also reveal if payments to local staff are at reasonable rates or not.
5. This type of behaviour is not restricted to international collaborative research. According to two reviewers for this paper and one of the HIC co-authors, it occurs in both HIC *and* LMIC RECs in relation to purely domestic applications. Consistent setting of expectations and standards by the REC is helpful to reduce this, according to one reviewer.
6. For example, although human samples imported into the UK must be handled in line with the provisions of the Human Tissue Act 2004, there is no requirement in UK law for demonstration that such samples have been subject to informed consent. The requirement for country of origin REC approval is restricted to best practice guidelines, e.g. Articles 62, 98–114, Human Tissue Authority (2017). There is widespread compliance with these guidelines; however, this remains a weakness in the system, especially in relation to potential ethics dumping.
7. For a discussion of the concept of reasonable availability in the context of international collaborative research, see Hawkins and Emanuel, 2008; and Lavery et al., 2007.
8. The academic authors of this paper are aware of historical instances where a chief provided assent in return for financial gain, creating possibilities for unethical researchers to bypass obtaining individual consent from participants. But single instances of unethical conduct or noncompliance with a particular procedure do not invalidate the procedure.
9. The two-snake caduceus design with wings is used as a symbol in medicine in many HICs.

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