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Challenges and Opportunities in Ensuring Ethical Research in Africa

Mantombi Maseme
University of the Witwatersrand
&
National Health Laboratory Service (NHLS)
masememr@gmail.com

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Abstract

The main ethical issues specific to the African continent research agenda relate to the vulnerability of African researchers, particularly as a result of inadequate resources, inadequate or lack of applicable legislation, and genetic variability of African populations that make samples from such populations most sought-after by researchers from other continents. This paper explores some of the ethical research challenges in Africa through an ethico-legal assessment of the literature and offers opportunities for addressing these challenges. The literature review findings revealed ethical dilemmas that include consent issues, cross-border transfer of samples and material transfer agreements, commodification of human material as well as benefit sharing. Based on these findings, opportunities for ethical research arise and these include benefit sharing such as researcher recognition and participating community study-related health benefits and well-defined agreements that consider appropriate specimen access and use. Significant changes in African research status quo are required to counter the effects of ethical research challenges, thereby ensuring sound ethical conduct and integrity in research. In addition to the noted opportunities, this paper also recommends monitoring of the fate of exported samples and proposes an ethical matrix that can be used by governments and institutions in addressing the highlighted research challenges in ethical decision making and policy intervention.

Keywords: *autonomy and trust; international collaborative research; human sample commercialisation; sample export; benefit sharing; ethical matrix*

Introduction

The ethical research challenges that are specific to the African context involve maleficence not only to research participants (interchangeably participants herein) themselves but also to researchers as well (Munung, Mayosi and de Vries 2017; Moodley and Singh 2016; Staunton 2016; South African San Institute 2017). Albeit these harms are not physical, they are problematic in my view because they can result in individuals being used as a means to an end in health research. According to Grietens, Ribera, Erhart, Hoibak, Ravinetto, Gryseels, Dierickx, O'Neill, Hausmann Muela, and D'Alessandro (2014), such ethical research challenges, resulted in the withdrawal of consent by research participants in Gabon as they feared that their samples might be stolen or sold for sorcery, thereby causing inexplicable illnesses. Moodley, Sibanda, February and Rossouw (2014) note South African research participants' anxiety and fears that their samples might be used for rituals under the guise of health research.

According to Hyder, Wali, Khan, Teoh, Kass and Dawson (2004), the researchers' challenges in Malawi include the lack of research review (ethical, technical, or scientific) by the Institutional Review Boards (IRBs), the Ministry or the Department of Health. The surveyed researchers reported

that some of the research conducted (15%), including 12% of United States (US) funded research and non-US funded research were also not reviewed. Munung *et al.* (2017) further note that African researchers also fear exploitation by their collaborators from High Income Countries (HICs) through exclusion from benefit sharing, particularly as a result of less capacity and resources than their funding collaborators. Whitworth, Kokwaro, Kinyanjui, Snewin, Tanner, Walport and Sewankambo (2008) assert that adding to these challenges are the legislative framework *lacunae* that hinder the much-needed research, mainly collaborations that involve human sample exchange and intellectual property (IP) rights. De Vries, Munung, Matimba, McCurdy, Oukem-Boyer, Staunton, Yakubu, Tindana and the H3Africa Consortium (2017) submit that such ethico-legal challenges relate to issues of sample storage in biobanks, ownership, sample, and associated data sharing as well as sample export, especially during research collaborations.

There has been a great deal of controversies and debates around international processes and guidelines that regulate research conduct, as observed by Bhutta (2002), with the concern that these instruments relate largely to physician principles rather than directly addressing research in developing countries. Notably, these international guidelines are not obligatory and national guidelines and legislation are the only legally binding instruments. De Vries *et al*. (2017) analysed regulatory frameworks for genomic and biobank research (which form part of health research) in 22 African countries and observed very specific guidelines in Malawi and Zambia for instance that impede genomic research in the two countries mentioned. The observation was in relation to informed consent which is also described differently in regulatory instruments across Africa in that some instruments are very detailed and descriptive considering different types of informed consent while other instruments are more abstract (De Vries *et al*. 2017). The general observation in this research was that the guidelines in the 22 African countries studied do not provide adequate guidance on genomic and biobank research.

In view of the discussion of the background presented thus far, this paper aims to provide an account of ethical research challenges and opportunities in Africa through an ethico-legal analysis. The normative issues which are explored include those that relate to participant consent (autonomy), sample transfer and inappropriate use as in commodification and benefit sharing. Regulatory frameworks of certain African countries in dealing with such aspects of research mentioned above are also examined. It is against the backdrop of the explored ethical research challenges that this paper also presents opportunities for overcoming these challenges. Accordingly, the paper presents a few proposals, namely, a mechanism for monitoring the fate of exported samples, increased community engagement (CE) empirical research, capacity building and benefit sharing as well as an ethical matrix for addressing the noted ethical research challenges.

Participant Autonomy and Trust

According to O'Neill (2001), the loss of trust in science and medical professions is often attributed to "supposed untrustworthiness'' of medical professionals and regulators who might want to pursue their own interests rather than those of the patients or the public. If such claims are true, then it follows that reducing the autonomy of any untrustworthy agent and institution would restore trust. The solution to balancing autonomy and trust lies in respecting human rights in order to respect individual autonomy (O'Neill 2001). Various African countries have promulgated laws that include bill of rights enforceable by law in which seeking informed consent from participants prior to conducting health research is a prerequisite (Nienaber 2007). Autonomy is the primary justification of informed consent and is aimed at avoiding harm as well as safe-guarding participant wellbeing; thus, autonomy can be thought of as a means and an end for the participants (Ursin 2009). Ursin (2009) further states that the challenge with requirements of informed consent that are grounded in autonomy, however, is that there may be ambiguity in conceptualizing autonomy. However, Manda-Taylor (2015) notes that autonomy is enhanced by the necessary information given to a patient or

research participant which is key to his or her decision-making ability. Healthcare professionals, in turn, are obliged by autonomy to keep their patients' information confidential (Manda-Taylor 2015).

In some African communities, particularly in rural areas, community members trust their leaders (chiefs) to make the decisions for participating in health research (Tindana, Kass and Akweongo 2006). Individual participant autonomy, although it can never be replaced, is thus influenced by this practice. Rural community chiefs in Ghana reported that they trust researchers and all of them said that "they had never rejected any research because they trust that the research is good for their community" (Tindana *et al.* 2006: 5). This finding is indicative not only of the important role that community leaders have in the consent process but also of the significance of engaging relevant communities prior to conducting research. Good CE structures are a requirement for the generating and maintenance of adequate understanding of the research context and relevant community (Boga, Davies, Kamuya, Kinyanjui, Kivaya, Kombe, Lang, Marsh, Mbete, Mlamba, Molyneux, Mulupi and Mwalukore 2011) as well as building trust between the community and researchers (CIOMS 2016). The Human Heredity and Health in Africa (H3Africa), a consortium involved in funding and conducting research of genomic and environmental determinants of disease in African populations (H3Africa 2020) and the Working Group on Ethics identified CE as one of the key ethical issues for promoting ethical research conduct (Tindana, de Vries, Campbell, Littler, Seeley, Marshall, Troyer, Ogundipe, Alibu, Yakubu and Parker as members of the H3A Working Group on Ethics 2015).

An Account of the Ethical Health Research Challenges in Africa

The minimum requirement for ethically sound health research is consistency with the basic principles of ethics that guide researchers to respect participants' *autonomy*, engage in research that will benefit participants (*beneficence*) and do no harm (*non-maleficence*) as well as treating participants fairly (*justice*) (Beauchamp and Childress 1994). As also noted by the World Health Organisation (WHO) (2001), there are other requirements for ethically sound research and these include prior ethical review by an independent body that will assess ethical compliance and as already alluded to, legal compliance.

There are factors which result in violation of the ethical principles, for instance, a person's ability to exercise his/her autonomy may be diminished by inadequate information or understanding or lack of freedom due to coercion or controlling influences (Tri-Council policy statement 2014). Several international guidelines speak to informed consent as far as ethical health research is concerned, *inter alia*, The Nuremberg Code which states that not only should adequate information be provided but also that the participants should be able to comprehend the involved subject matter elements in order to enable the understanding required for sound decision-making (British Medical Journal 1996). The WHO (2001) observed that most of the research participants in Africa are poor and illiterate, and therefore extremely vulnerable to violation. The Council for International Organizations of Medical Sciences (CIOMS) (2016) asserts:

> vulnerability involves judgments about both the probability and degree of physical, psychological, or social harm, as well as a greater susceptibility to deception or having confidentiality breached (CIOMS, 2016: 57).

The CIOMS (2016) further notes that the incapability, to a certain extent, of protecting their own interests is the reason that persons are vulnerable, hence the role of Health Research Ethics Committees (HRECs) in order to evaluate health research risks and benefits alike. Complicating the issue of consent even further is the different models of informed consent that include broad consent. In South Africa (SA), the National Department of Health's (NDoH) Ethics in Health Research Principles, Processes and Structures (2015) defines broad consent as consent for future research use of samples. This model of informed consent is typical of biobank research which globally has

inadequate ethico-legal frameworks. De Vries *et al*. (2017) note that broad consent is prohibited in countries like Zambia while Malawi and Tanzania neither specifically discuss nor prohibit this consent model.

Chen and Pang (2015) point out that international collaborative research, particularly in the context of biobank and genetic research, is negatively impacted by issues that include poor or absent ethico-legal frameworks (including cross-border) and unfair benefit sharing that constitute exploitation. Campbell and Tishkoff (2010) note that African populations have the highest level of genetic variation as a result of a number of genetic and phenotypic adaptations that have evolved in Africans in response to diet, variation in the environment as well as exposure to infectious disease across the continent. This genetic variability makes African samples "highly sought after internationally", resulting in "unidirectional flow of samples out of Africa" (Moodley and Singh 2016: 2) that have raised concerns around exploitation of vulnerable communities and countries. The resources for research in Africa are limited, hence researchers often seek funding from independent agencies, and these are often international funders in HICs that are part of the collaborations). Maseme and Mahomed (2020) argue against exchanging human samples for funding based on reasoning that there is

i. An infringement of participants' dignity and rights,
ii. Infringement of ethical principles by disregarding beneficence and justice and
iii. Challenged professionalism as well as participant-researcher social contract which has the potential for participant exploitation due to vulnerability inherent in the trust relationship.

By inference, exchanging human materials (samples) for money (funding) "reduces human beings to mere objects or commodities" (Maseme, 2021: 2). Rachels (2003) agrees with Immanuel Kant that human beings should rather be used as an end in themselves and not as a means to an end (Rachels 2003). She further argues that the dignity or "intrinsic worth" of human beings makes them valuable "above all price" (Rachels, 2003: 130). In order to prevent such maleficence in human sample and associated data sharing, a contractual agreement such as a Material Transfer Agreement (MTA) is necessary, particularly where there are no adequate ethico-legal safeguards. A MTA documents and directs material transfer between parties involved as well as conditions for material usage (SA National Material Transfer Agreement 2018) as well as terms for safe-guarding participants' rights (Bennett, Streitz and Gacel 2007). Moodley and Singh (2016) observe that sample sharing is a challenge in Africa as some countries have national MTAs while others do not. The complication with this challenge results in issues of benefit sharing and contested sample ownership or custodianship.

A few themes relating to ethical research challenges have emerged from the preceding discussion and these include:

i. Consent issues particularly in relation to broad consent
ii. Sample transfer and material transfer agreements
iii. Commodification (commercialisation) of human material (samples and associated data) and
iv. Benefit sharing which relates to sample ownership and IP.

All these issues are a direct reflection of infringement of the principles of ethics and in order to prevent such challenges, appropriate laws in that regard are requisite.

Regulatory Frameworks

Despite the potential for the noted challenges, Nabyonga-Orem *et al*. (2021) report on a lack of specific laws for guiding health research conduct in up to 34.3% (12 out of 35) member states included in the study (Botswana, Burundi, Cape Verde, Cote d' Ivoire, Democratic Republic of the

Congo, Eritrea, Ethiopia, Guinea-Bissau, Mauritania, Namibia, Seychelles, South Sudan) of the WHO African region. Such laws were still in draft format in 14.3% of the countries (Lesotho, Liberia, Niger, Sierra Leone, Swaziland). This unsettling observation raises myriad of questions on the protection of research participants' rights as well as the integrity of health research in the countries concerned and there should be a clear call for those in government and policy decision making to attend to this. In those countries that have health research legislation, some of the gaps are noted below.

On broad consent for future research use of samples, as noted by De Vries *et al.* (2017), there are cases where there is permission with conditions, unclear guidance (neither permitted nor prohibited), where broad consent is either explicitly or implicitly permitted through suggestive wording. According to Scott *et al.* (2012), the central issue relating to broad consent use is "whether broad consent can ever truly be informed and therefore fulfil the established principles of consent". The World Medical Association Declaration of Taipei on ethical considerations regarding health databases and biobanks (2016) gives guidance on validity on this type of consent and this includes giving participants adequate information on, among others, the purpose of the collection, risks and burdens, access, and privacy rules, and when applicable, benefit sharing, commercial use and material transfer to other institutions or countries.

The South African National Materials Trade Agreement of Biological Materials (SAMTA, hereinafter) was gazetted in 2018 (SAMTA 2018) hopefully alleviating strong opinions and concerns raised by SA researchers about not being respected by their collaborators from HICs who resist MTA use as noted by Moodley and Singh (2016). The SAMTA is an important milestone as it also provides for benefit sharing and material ownership and custodianship (SAMTA 2018). Sample export in Africa is generally a problem as some countries have MTAs while others do not (Moodley and Singh 2016).

Moodley and Kleinsmidt (2020) raise a controversial issue on alleged commercialisation of African sample associated data which according to a whistle-blower (fired from Singer) was used to make gene chips through negotiations between Singer and Thermo Fisher Scientific. Gene chips or 'microarrays' are "tiny glass slides, each containing DNA from a different gene" (Moodley and Kleismidt: 2). Microarray tests are used for rapid genetic testing of samples and cheaper than whole genome sequencing (Moodley and Kleinsmidt 2020). Researchers from Stellenbosch University, which was one of the research sites, demanded that the samples be returned based on the reasoning that they and the participants did not grant explicit consent for sample commercialisation and that this was not part of MTA with the American collaborator (Moodley and Kleinsmidt 2020). This finding highlights the need for monitoring of the fate of exported samples from SA. Section 60 of the SA National Health Act 61 (2003) protects against commercialisation of human samples.

The Necessity of a Mechanism for Monitoring of the Fate of Exported Materials and Alternative(s) to such a Mechanism

Tindana, Molyneux and Parker (2014) highlight African researchers' and HRECs' concerns about the lack of feedback on the fate of exported samples that are part of collaborations, which in turn leads to suspicions that samples may be used for other purposes without the knowledge of the contributing researcher... local researchers might assume that their samples have been stored in these external laboratories when in reality, they have been used up and destroyed after the analysis (Tindana *et al.*, 2014: 6).

They further note that although some of the stakeholders have suggested that there should be host institution research capacity building in order to enable much of the research processes to be conducted locally, there is an acknowledgement that no level of local capacity can completely eliminate sample export. Dhai, Mahomed and Sanne (2015) argue that these challenges should not impede on human health research because networking and sharing of data maximise research

potential through desired statistical power attainment, addressing resource constraint and some of the financial issues as well as being for the common good. It is for this reason that a mechanism for monitoring of the fate of exported samples is required.

The proposed framework should be mandatory for monitoring of exported samples by the transferring institution through regular material inventory monitoring by appropriate Standard Operating Procedures (SOPs) and a notifiable or a reporting system co-ordinated by a nation's health research ethics council. Some alternatives for monitoring of the fate of exported samples in the face of inadequate ethico- legal frameworks include the following:

i. Measuring actual research output against the number of materials exported through return of research results to the institution that transferred the samples by the recipient. The accountability for the amount of material transferred should be monitored through keeping an inventory on a robust Laboratory Information Management System (LIMS) with an audit trail.
ii. Cross-border transfer material stewardship through mandatory discarding of remnant materials.

Future Opportunities for Addressing Ethical Health Research Challenges

Against the backdrop of the noted challenges, in addition to the mechanism proposed above, opportunities arise in the form of CE to enable communities to understand better health research, research capacity building as a means to counter resource-related exploitation through benefit sharing and translating research recommendations into amendments in national legislation and regulations.

Community engagement

The plethora of literature on CE guidance and challenges in general health research which includes genomic and biobank research is undisputed (Tindana *et al*. 2015; Reynolds and Sariola 2018, Tindana *et al*. 2017, Lavery, Tinadana, Scott, Harrington, Ramsey, Ytuarte-Nunẽ and James 2010). The H3Africa CE guidance document is specific to the African context and is useful in that regard as it takes into account "community gate keepers" (H3Africa Guidelines for Community Engagement Version Two, 2017: 9) in the consultation process and these include chiefs, traditional leaders, community and religious representatives, opinion leaders and the like, as a means of gaining access to the community and approaching individual members of the community before research implementation (H3Africa Guidelines for Community Engagement Version Two 2017). The paucity of literature on empirical studies for CE in biomedical research, which genomic and biobank research is a part of, suggests a research gap in that regard.

One way of addressing this challenge could be by incorporating CE in research focus areas at research institutions as one of the key performance indicators (KPIs) objectives for biomedical researchers. Such a method of promoting research is likely to succeed due to the potential for incentive in the form of recognition for the researcher through increased research output and the resultant possibility for increased publications which is directly linked to researcher performance matrices.

Effective collaborations for CE is another way in which empirical research output could be enhanced in this area. This could be particularly relevant for wide access to regions that would not have been otherwise reached. Collaborative CE partnership could also be beneficial in promoting research networks, as well as increasing capacity, particularly in terms of bringing together researcher expertise and facilitating funding in line with research ethics principles while avoiding dual loyalty.

Research capacity building and benefit sharing

As already mentioned, funding is a major constraint to research on the continent and one of the ways this can be improved is through increased budgetary allocation for health from a country's national budget. In South Africa, for instance, major health research entities such as the National Health Laboratory Service (NHLS) and its subsidiaries as well as the Medical Research Council (MRC) are partly funded at the macro-level by National Treasury. (National Treasury Republic of South Africa 2019). This funding has been allocated for developing young scientists in all health professions, surveillance of communicable diseases and outbreak response as well as occupational health training and research (National Treasury Republic of South Africa 2019). The administration for actual research project funding is however done at the meso-level by the respective organisations. In practice, some of the common reasons for research project application rejections are due to the researcher(s) not being qualified enough (e.g. not in possession of a doctoral degree), or being in an older age group irrespective of their level in the profession and/or funding being limited only to consumables and not study-related transport.

Allocating benefits fairly and equitably relates to distributive justice. The Belmont report provides useful guidance in terms of who ought to receive research benefits and bear its burdens. According to the Belmont report, (1979:5), the formulations for distribution of benefits and burdens are:

i. To each person an equal share
ii. To each person according to individual need
iii. To each person according to individual effort
iv. To each person according to societal contribution, and
v. To each person according to merit

This concept can be translated to the African context health research to develop an ideal benefit sharing model that considers:

i. human capacity building in the form of training and mentoring medical scientists and health science researchers
ii. infrastructural resource capacity building through access to funding,
iii. shared IP rights (including shared authorship) where applicable and
iv. benefits for participating communities through provision of study-related ancillary services (Maseme 2020).

While international guidelines provide a useful guide for ethical conduct, legally binding frameworks are of paramount importance in ensuring ethical conduct and hence inadequacies in the respective country regulations ought to be addressed. In order to ensure quality control mechanisms, scientific policy advice to governmental decision makers should be peer reviewed advice based on evidence and reason (Inter-academy Partnership, 2016).

The onus is on the respective countries themselves to formulate and implement such regulations. Until such a time exists where these inadequacies have been addressed, the competing interests of the stakeholders involved in sharing materials ought to be discussed at the beginning of such collaborations, ought to be discussed at the beginning of such collaborations with mutually agreed terms as a requirement (Maseme and Mahomed, 2020: 107).

The highlighted opportunities can be incorporated in the form of an ethical matrix which is a concept that was originally created in the 1990s by Ben Mepham (Forsberg 2004). This concept is inspired by the four principles of biomedical ethics and interprets ethical concerns according to all situations for the affected parties in an ethical deliberation process (Forsberg 2004). According to Mepham *et al.* (2006) an ethical matrix can be used by governmental policy decision makers and institutional working groups or advisory committees to achieve a number of outcomes that include:

raise awareness of a wide range of ethical issues, encourage ethical reflection, provide a common basis for ethical decision-making, identify areas of agreement between individuals who might

nevertheless differ in their overall judgements, clarify the basis of disagreements, and make explicit the reasoning that underpins any ethical decisions (Mepham, Thorstensen, Tomkins and Millar, 2006: 6).

Even though the ethical matrix is a concept which was originally developed for sound ethical decision-making in the food and agriculture technology industry, the concept can be applied in health research arena for ethical decision making and policy intervention to address the identified research ethics challenges and legal lacunae because the principles apply in the same way. Table 1 below illustrates a proposed generic ethical matrix for health research based on the points discussed in this paper.

Table 1: Generic ethical matrix for health research

Respect for:	**Wellbeing**	**Autonomy**	**Fairness**
Research participants	Minimizing research risks while maximising benefits Study-related healthcare services IP benefits where applicable	Informed consent	Fair health research laws
Researchers	Research capacity building through training, mentoring and access to infrastructural resources IP benefits where applicable Shared authorship where applicable	MTAs	Adequate health research laws
Communities	Community engagement	Freedom to choose whether to participate in future research	Equal treatment between research volunteers and those that choose not to participate
Governments and research institutions	Increased research outputs	Acknowledgement of their role in promoting ethical conduct	Sustainability

Source: Adapted from Mepham *et al.* (2006)

Conclusion

The discussion in this article indicates that health research challenges in Africa are linked to withdrawal of consent, lack of IRB review, sample transfer and misuse as in commodification and benefit sharing. Lack or inadequate oversight as well as resource related challenges also impede on ethical research on the continent. Adequate regulatory frameworks are essential in preventing research participant exploitation and there are still a large number of African countries that need to finalise gaps in their health research legislation and frameworks. Regulatory framework gaps that have been identified include: a need for clear direction on the use of broad consent, lack of MTAs for some countries and commercialisation of exported samples. Against the backdrop of the noted challenges, opportunities arise in the form of monitoring of exported samples in preventing commercialisation, CE to enable communities to better understand health research, research capacity building as a means to counter resource-related exploitation and addressing benefit sharing as well as translating research recommendations into amendments in national legislation and

regulations. Monitoring of the fate of exported samples by the transferring institution should be through SOP based regular material inventory monitoring and a notifiable or a reporting system co-ordinated by a nation's health research ethics council.

An alternative mechanism for monitoring of exported samples is by measuring actual research output against the number of materials exported via return of research results to the institution that transferred the samples by the recipient as well as cross-border transfer material stewardship through mandatory discarding of remnant materials. To counter the scarcity of CE in biomedical research, this area can be enhanced through incorporating CE in research focus areas at research institutions as one of the KPI objectives for biomedical researchers as well as through CE collaborations. An ideal benefit sharing model for the African context is one which considers: capacity building for human and infrastructural resources through researcher training and funding respectively, shared IP rights (including shared authorship) and study-related ancillary services for participating communities. An ethical matrix can be used by governments and institutions in addressing the noted research challenges in ethical decision making and policy intervention. The proposed matrix for health research considers the principles of respect, wellbeing, autonomy, and fairness for all research stakeholders, namely: participants, researchers, communities as well as governments and research institutions.

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