Consent to and authorisation of the export and use of human biological specimens for future research – perspectives from three African countries

Annelize Nienaber[*]

Abstract

In light of previous exploitation, less developed countries, understandably, are suspicious of any effort that weakens in the name of scientific progress the highly-valued notions of individual autonomy and informed consent. When researchers import human biological specimens for the purposes of research which will benefit those in developed countries, the charge of scientific imperialism is automatically levelled. Using three countries in Africa as a starting point for the study, the article examines the consent and authorisation requirements for the export of human biological specimens, gathered from health research in the developing world, for subsequent research projects in the developed world. The article concludes that there is an urgent need to strengthen the ethical and legal framework in Africa which governs consent to, and authorisation of the export and use of human biological specimens for future research.

INTRODUCTION

Human biological specimens – such as tissue, organs, blood and genetic material – increasingly are used in biomedical research which seeks the physiological and genetic causes and cures for disease. Some biological specimens are donated expressly for research purposes; more often, however, the samples are collected during research projects or diagnostic procedures and retained for use in future research.[1] Because of a lack of facilities and

[*] Associate Professor of Law: Faculty of Law, University of Pretoria. Legal Advisor, Faculty of Health Sciences Research Ethics Committee, University of Pretoria. Advocate of the High Court of South Africa.

[1] BS Elger & AL Caplan 'Consent and anonymization in research involving biobanks. Differing terms and norms present serious barriers to an international framework' (2006) 7 *EMBO Reports* 661 at 661–662.

capacity, specimens obtained from research and other procedures in Africa and other parts of the developing world, regularly, are exported to countries in Europe and America for further research. As well, these specimens may be stored in tissue banks or repositories until they are needed in the future.[2] Future research on these specimens takes a number of forms, including genetic, epigenetic, pharmacogenetic or extragenetic research.

In the context of a history of accusations of unethical or illegal conduct by health researchers[3] and of so-called 'research imperialism', which have been levelled against those who undertake research in Africa but who do not share the benefits of that research with African research participants and scientific collaborators, the exportation of biological specimens for future research raises important and complex questions with regard to such elements as consent, capacity building, intellectual property rights, community engagement and benefit sharing.

The focus of the article is on research participant consent, as well as government authorisation of the export of biological specimens for future research.[4] Different terms are used in the literature for the different forms of research participant consent relevant to the export and future use of biological specimens in research. Broadly speaking, participant consent takes a number of forms, which range from express or implied *general* consent,[5] in which the participant either has or is deemed to have consented to the export and future use of their samples for any research project at any future

---

2 *Ibid.*

3 See *eg* M Angell 'The ethics of clinical research in the Third World' (editorial) (1997) 337 *New England Journal of Medicine* 847; H Varmus & D Satcher 'Ethical complexities of conducting research in developing countries' (1997) 337 *New England Journal of Medicine* 1003; A Nienaber 'The utility of international human rights law on informed consent in the protection of clinical research participants in Africa: "the road less travelled"' (2007) 2 *SA Public Law* 422; A Nienaber 'The protection of participants in clinical research in Africa: does domestic human rights law have a role to play?' (2008) 1 *African Human Rights Law Journal* at 138–163; and P Lurie & SM Wolfe 'Unethical trials of interventions to reduce perinatal transmission of the Human Immunodeficiency Virus in developing countries' (1997) 337 *New England Journal of Medicine* 854 at 854–856.

4 Note that some scholars argue that it is impossible to obtain true informed consent for future research where human biological specimens are concerned because such consent can never be really informed: see *eg* K Hoeyer *et al* 'Informed consent and biobanks: a population-based study of attitudes towards tissue donation for genetic research' (2004) 32 *Scandinavian Journal of Public Health* 224 at 224–225; at 229.

5 Also called 'broad' consent in the literature.

point in time;[6] to express *specific* consent for specific future research into research projects directly or indirectly related to the present research project or the specific disease (for example, future research investigating the causes of a specific type of breast cancer);[7] to *restricted* consent[8] that is only valid for the present research study and which forbids use in any future research project.[9]

The article examines the regulation of the export and future use of biological specimens for research in respect of three African countries: Nigeria, Kenya and South Africa. First, the phenomenon of international collaborative clinical research is surveyed in order to sketch the background against which such research takes place in Africa and during which biological specimens are exported. Further, the vulnerability of research participants to exploitation in an African-country research context is outlined. Second, the requirements for consent to, and authorisation of the export and future use of biological specimens presenting in Nigeria, Kenya and South Africa are discussed, and conclusions are based on this comparative survey. Third, the role of research ethics committees in protecting the interests of research participants is described. Finally, the article offers recommendations as to measures which would protect against potential exploitation developing country research participants who donate biological specimens for future research.

A number of international research ethics documents and conventions aim to regulate consent to the future use of human biological specimens.[10] The

---

6 RJ Bryant *et al* 'Ownership and uses of human tissue: what are the opinions of surgical in-patients?' (2008) 61 *Journal of Clinical Pathology* 322 at 322; J Wheeler *et al* 'Experiences from the front line – routine consenting of surplus surgically removed tissue' (2007) 60 *Journal of Clinical Pathology* 351 at 351; D Wendler 'One-time general consent for research on biological samples' (2006) 332 *British Medical Journal* 544 at 544–547; D Wendler & E Emanuel 'The debate over research on stored biological samples: what do sources think?' (2002) 162 *Archives of Internal Medicine* 1457 at 1457–1458.

7 Wendler & Emanuel n 6 above at 1457.

8 Also referred to as 'specific informed consent' in the literature.

9 E Savaterra *et al* 'Banking together: a unified model of informed consent for biobanking' (2008) 9 *EMBO Reports* 307 at 309; Wendler & Emanuel n 6 above at 1457.

10 See *eg* the World Health Organization's Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells and Fluids in Research (2003); Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services (1997); the Council for International Organizations of Medical Sciences' International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002); the United Nations Educational, Scientific and Cultural Organization's International Declaration on Human Genetic Data (2003); the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with

present discussion is limited to a comparative study of domestic or municipal ethics documents and legislation, therefore these international documents are not discussed.[11]

Note that the two terms used in the title of the article denote different actions: 'informed consent' to the export and use of human biological specimens for future research is given by the individual research participant; 'authorisation' of the export and use of human biological specimens for future research is undertaken by a government department or agency. The article investigates both aspects.

Below is an account of the background against which the export and future use of human biological specimens should be viewed, as well as of the potential for exploitation of developing country researchers and research participants.

BACKGROUND

International collaborative research

Clinical research illustrates how globalisation has resulted in an increase in international collaborative research, that is, researchers and institutions collaborating in research that is conducted across national borders.[12]

International collaborative research (such as multi-centre studies), in which clinical trials are conducted in more than one country; or instances in which the sponsor is from one country (usually developed) and the principal investigator (PI) and trial participants are from another (usually less developed) country, often require that biological specimens be exported for further research in the developed country. In most cases this is because the less developed country is lacking the technology and expertise to analyse the samples. The trial sponsor may export and then store biological specimens in the developed country for use in research in another or future project.

Regard to the Application of Biology and Medicine (1997); Treaty Series No 195, Human Rights and Biomedicine Protocol on Biomedical Research (2005); and Recommendation 4 on Research on Biological Materials of Human Origin (2006).

11 For an overview of the international regulation of consent to the export and future use of human biological material, see A Nienaber 'The international regulation of the export and future use of human biological specimens' (forthcoming).

12 See generally, SE Geller *et al* 'Conducting international collaborative research in developing nations' (2004) 87 *International Journal of Gynaecology and Obstetrics* 267 at 267–269.

International collaborative research takes many forms and does not have to involve clinical trials. A strict definition of international collaborative research requires no more than that researchers from different countries collaborate on the same project. Such collaboration may involve the sharing of ideas, the joint undertaking of literature studies or international comparative studies. These examples of international collaborative research do not necessarily present ethical or legal difficulties.

International collaboration involving clinical trials of a new intervention or drug in different countries, on the other hand, raises issues such as differing standards of care in different settings, intellectual property rights, risk sharing and the fair distribution of the burdens and benefits of research. Multi-centre studies, as a sub-species of international collaborative research, have the potential to present a multitude of problems.[13] Such collaborations pose unique and complex problems that must be addressed to ensure that international research is conducted with strict adherence to ethical principles, offers direct benefit to the research subjects, and has the potential or adoption of positive findings to other members of the population.

A multi-centred study is conducted simultaneously by several investigators at different centres or sites, using standardised methods and a standardised protocol.[14] The different sites may be situated in any number of countries, each with its own PI.

A significant level of international drug efficacy and safety research is undertaken by means of multi-centre studies, in which the trial sponsor (a pharmaceutical company) is based in country A, and the clinical trials are conducted by PIs in countries A, S, T, U, V, X, Y and Z. The international collaborators in such research are host country institutions (usually the sponsors of research – the pharmaceutical company in country A), collaborating country institutions (academic institutions or research entities in countries A, S, T, U and so on), researchers from both the host country and collaborating countries, research participants and their communities in the collaborating countries or in both the host and collaborating countries.

International collaborative research may be highly beneficial. However, in the past, multi-centre clinical trials, on occasions, have resulted in the

---

13 *Id* at 268.

14 Guideline 7 of Department of Health (2000) Guidelines for good practice in the conduct of clinical trials in human participants in South Africa.

exploitation of researchers and clinical trial participants.[15] Milford *et al* comment as follows:[16]

> Research in developing countries is often financed by well-resourced, developed countries and conducted in vulnerable host communities with diverse cultural backgrounds. Moreover, multinational research is frequently conducted according to the regulatory frameworks of wealthier sponsor countries, which may be inappropriate to host country conditions and raise ethical concerns about potential exploitation of host communities and participants, insensitivity to community ethos, the scope of sponsor-investigator obligations, and the appropriate communication of research results to participants.

Vulnerability of research participants to exploitation

Poverty, a lack of resources, gender inequality and a lack of access to health care often are the reality in communities in which international collaborative research takes place in the developing world. In the presence of these factors, these communities are vulnerable to exploitation.

Communities in which these factors are present are not without fail vulnerable to exploitation in research, nor are communities in which these factors are absent immune to being exploited. In this context, vulnerability is a matter of degree, where certain communities, because of their characteristics, are more vulnerable to exploitation than others. The UN guidance document, entitled 'Ethical considerations in HIV preventive research', similarly, asserts that the 'developing/developed' terminology for assessing risk of harm and exploitation is of limited value, as it refers primarily to economic considerations which are not the only relevant factors in research.[17] Therefore, it is important to identify the *particular* aspects in a social context that create conditions for exploitation, or for increased vulnerability of participants.

To exclude from research individuals or groups in this category necessarily results in their being denied access to the benefits which obtain from research conducted in their community. In the case of research conducted in Africa, these include the important benefits of developing drugs or treatment options

---

15 See sources cited in n 3 above.

16 C Milford *et al* 'Resource and needs of research ethics committees in Africa: preparations for HIV vaccine trials' (2006) 28 *IRB: Ethics & Human Research* 1 at 1–2.

17 UNAIDS Guidance document (2000) *Ethical Considerations in HIV preventive vaccine research* at 23.

geared to Africa, as well as other benefits such as increased access to health care.

The effort to protect vulnerable communities sometimes amounts to paternalism.[18] With reference to the 1993 version of the CIOMS guidelines, Macklin comments: '[t]his recommendation – designed to protect vulnerable populations from harm in biomedical research – was resented by developing country researchers and health advocates in these regional consultations'.[19]

To sum up, in seeking the protection of vulnerable communities from exploitation, the following should be taken into account: research in vulnerable communities is not by definition exploitative and unethical; measures may be taken in vulnerable communities to exclude or limit exploitation; vulnerable communities should not be denied the opportunities arising from research participation; and paternalistic attitudes are denigrating.

The outline above of the context of international collaborative research and the vulnerability of developing country research participants is presented to contextualise issues of informed consent to and authorisation of the export and future use of human biological specimens. The discussion turns to a comparative study of existing national law and the ethical guidelines in the three countries under consideration.

COMPARING THE REGULATION IN THREE AFRICAN COUNTRIES: NIGERIA, KENYA AND SOUTH AFRICA

The choice of countries to be used in a comparative study was limited by a general lack of regulations and legislation pertaining to the issue in many African countries. As well, access to materials is limited. Three countries were chosen: Nigeria from West Africa; Kenya from East Africa; and South Africa from the Southern African region.

Nigeria

Health research in Nigeria is governed by the National Health Act, 2009. At present, no legislation specifically governs the situation of research participants consenting to the future use of their biological specimens.

---

18 R Macklin *Double standards in medical research in developing countries* (2004) at 1–495, 480.

19 *Id* at 4.

In Nigeria, the agency responsible for the administration of drugs and devices is the National Agency for Food, Drug Administration and Control (NAFDAC),[20] established by Decree 15 of 1993. Nigeria's National Health Research Ethics Committee is responsible for overseeing all health research undertaken in Nigeria.[21] National health research guidelines, in the form of the National Code of Health Research Ethics, 2007, govern health research in Nigeria.

The National Code of Health Research Ethics, 2007, designates the National Health Research Ethics Committee (NHREC or Committee) as the supreme body responsible for monitoring adherence to guidelines that govern ethical research practices in Nigeria, so ensuring the protection of research participants.[22] NHREC was inaugurated in October 2005. The Committee's predecessor, the Health Research Ethics Committee, had been in existence since the early 1980s. The Nigerian NHREC is to:[23]

> (a) set norms and standards for conducting research on humans and animals, including clinical trials; (b) adjudicate in complaints about the functioning of health research ethics committees and hear any complaint by a researcher who believes that he has been discriminated against by any of the health research ethics committees; (c) register and audit the activities of health research ethics Committees; (d) refer to the relevant statutory health professional council, matters involving the violation or potential violation of an ethical or professional rule by a health care provider; (e) recommend to the appropriate regulatory body such disciplinary action as may be prescribed or permissible by law against any person found to be in violation of any norms and standards, or guidelines, set for the conduct of research under this Act; and (f) advise the Federal Ministry of Health and State Ministries Health on any ethical issues concerning research on health.

Section A of Nigeria's National Code of Health Research Ethics, 2007, (Nigeria's National Code or the Code), directs that the Code applies to 'all health research involving human participants, conducted, supported or otherwise subject to regulation by any institution in Nigeria'[24] – thus, all health research undertaken in Nigeria.

---

20 See http://www.nafdac.gov.ng.

21 See http://nhrec.net.

22 Federal Ministry of Health Planning and Research National Code of Health Research Ethics (2007) at 10.

23 National Code of Health Research Ethics (2007) at 11–12.

24 *Id* at 12.

Guideline (f) of Section F of Nigeria's National Code governs informed consent by participants to participation in research.[25] It prescribes the requirements that have to be met for consent to be valid, including requirements regarding the nature of the information that needs to be provided to participants; the design of the consent process; the requirements that informed consent documents or forms need to comply with (including font type, font size, spacing and paper size); and the specific information that need to be included in consent forms (such as the potential risk(s), costs, benefits, confidentiality, alternatives to participation, and so on).[26] Guideline (h) states as a requirement of ethical research that nothing may be done 'to undermine the trust relationship that is at the heart of the researcher(s)-participant(s) relationships'.[27] Unfortunately, consent by research participants to the exportation of their biological specimens is not mentioned, nor, in the section of the Code dealing with informed consent, is the form such consent should take mentioned.

Guideline (I) supports the Code's aim of protecting Nigeria's research participants. It requires that 'the interest of participants, researchers, sponsors and communities … be protected', so that the 'research has lasting impact, transfers technology where appropriate, contributes to capacity building and demonstrates respect for socio-cultural and other differences'. Specifically, care should be taken to consider, protect and compensate the intellectual property rights, indigenous knowledge and the contributions of all parties in cases 'where research leads to tangible or intangible benefits'.[28] Although it is not explicitly stated, the clause may be interpreted as guarding against exploitation that may result from the unauthorised and uncontrolled export of human biological specimens.

The Code governs the process for reviewing multi-institutional research. It stipulates that in the conduct of multi-institutional research each institution is responsible for safeguarding the rights and welfare of human participants in its institution and for complying with the Code.[29] Especially relevant is clause (n) of the Code which governs a 'materials transfer agreement' (MTA). It stipulates that the 'transfer of samples and biological materials such as animals, herbs and plants out of Nigeria shall require a Materials Transfer Agreement […] detailing the type of materials, anticipated use,

25 *Id* at 41.
26 *Id* at 42.
27 Clause (h).
28 Clause (I).
29 Clause (m).

location of storage outside Nigeria, duration of such storage, limitations on use, transfer and termination of use of such materials subject to any law, regulations and enactment in Nigeria'.[30] The Code states the purpose of a MTA to be the protection of the interests of local researchers and Nigeria's human and natural resources in all its biodiversity, as well as prescribing how they can be used legitimately,[31] and declares that the 'interests of all relevant parties, human and community participants in research and the Nigerian nation are protected from exploitation and egregious harm' by a MTA.[32] These requirements in Nigeria's National Code of Health Research Ethics regarding a MTA clearly are directed at protecting Nigeria's researchers and resources from exploitation, since no export of any biological specimens is allowed unless a MTA is in place.

The Code prescribes the technical requirements that the MTA must meet. A MTA must be signed by all parties involved in the research, including local and international PIs, heads of local institutions, research sponsors and other relevant parties.[33] It is unclear who is to be considered a 'relevant party'.

The Code places on individual local institutional health research ethics committees (HRECs), the responsibility to review the MTA to satisfy consistency with the stated objectives of the research, the contents of the informed consent documents and the principles enumerated above.[34] Individual HRECs have a duty to ensure that the MTA corresponds to the contents of the informed consent documents signed by research participants. Although not expressly mentioned in the Code, it is assumed that the HREC will compare the nature and extent of the consent to the collection of the biological specimens noted in the participants' informed consent documents with the anticipated use of their biological specimens after export. Despite such possibility, it is important to note that the exact nature or formalities required for the informed consent of the research participants from whom the specimens or samples are obtained is not stipulated. Neither does the Code set out the different types of consent to the export and future use of biological specimens, or mention explicitly what aspects of the consent documents need to be consistent with the MTA.

---

30 Clause (n).
31 *Ibid*.
32 *Ibid*.
33 Clause (n) a.
34 Clause (n) b.

A HREC grants provisional approval, pending the submission of MTA to NHREC and receipt of acknowledgement from the NHREC.[35] The final approval by an institutional HREC for research involving international transfer of Nigerian samples is granted only after all other criteria stated in the Code for approval of research have been met and upon receipt of acknowledgement by the NHREC of the MTA.[36] As well, the Code makes clear that the MTA does not vitiate the right of research participants or communities to request that their samples be withdrawn from research according to the terms of the informed consent process.[37]

It is clear from the above discussion that Nigerian authorities are aware of a potential for exploitation when human biological specimens are exported, as well as of their responsibility to protect research participants from such exploitation. However, although there is provision in Nigeria's National Code of Health Research Ethics for the requirements of informed consent, no mention is made of the exact nature of participants' consent to the export and future use of their samples. Ethics committees are responsible for correlating that research participant consent matches that described in the MTA; however, no mention is made of what constitutes valid consent by a research participant to the export of her samples, or of the different forms of consent that are possible.

With reference to government agency authorisation of the export of biological specimens, the Code nominates the NHREC as the agency so empowered. Authorisation depends upon the receipt of a MTA that meets the stated requirements.

Kenya

The Science and Technology Act of 1979 governs health research in Kenya.[38] In terms of the Act, the National Council for Science and Technology's (NCST) promulgated Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya (NCST Ethics guidelines) in 2004.[39] The Ministry of Health's Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines of 2005 (Vaccine

---

35 *Ibid*.
36 Clause (n) f.
37 *Ibid*.
38 Republic of Kenya,. The Science and Technology Act (1980).
39 Republic of Kenya, National Council for Science and Technology, NCST 45. Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya (2004).

development guidelines) are relevant as well.[40] The NCST and the Ministry of Education, Science and Technology through the Department of Research Development, are the institutions which oversee research in Kenya.[41] The Kenya HIV/AIDS Vaccine Subcommittee and the Pharmacy and Poisons Board, as well as the Kenyan Ministry of Health (governing hospitals such as the Kenyatta National Hospital), Kenya Medical Research Institute (KEMRI), as well as various universities, are also of interest.

The NCST Ethics guidelines aim to provide heath researchers in Kenya with a systematic and coherent framework for determining whether clinical research in Kenya is ethical.[42] Guideline 2 of NCST Ethics guidelines requires that health research in Kenya be reviewed by an independent ethics review committee. Guideline 6 provides for informed consent to research participation, as well as for proxy consent.

Guideline 15 deals with informed consent to epidemiological studies, and provides for the possibility of doing away with individual informed consent in situations an ethics review committee deems appropriate. In the Guidelines there is reference to research into anonymous 'left-over' samples of 'blood, urine, saliva, tissue specimens', but no mention is made of any special procedures for consent to the future reuse of such samples or for their export. It appears as if guideline 15 does not require individual informed consent for future research into such samples, with the requirement that the samples are anonymous.

Under the heading 'externally sponsored research', the NCST Ethics guidelines require that externally sponsored research be responsive to the health needs of Kenya.[43] Such research must address health problems that are important in Kenya, and the sponsoring agency agrees in advance of the research that any product developed through the research is made reasonably available to the inhabitants of the community in which the research was conducted. The agreement of the sponsoring agency is encouraged further to maintain health services and faculties established for purposes of the study and to assist in developing capacity for similar research in Kenya.[44]

---

40 Republic of Kenya, Ministry of Health. Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005).
41 Foreword, NCST Ethics guidelines.
42 NCST Ethics guidelines at 1.
43 NCST Ethics guidelines at 16.
44 *Ibid*.

In 2006 the Ministry of Health published the Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (Vaccine development guidelines). The guidelines have among their objectives facilitating research and the development of vaccines that can either prevent HIV infection or delay the progression of the disease, as well as building a national consensus on a comprehensive, well-co-ordinated, long-term strategy for developing and evaluating safe, efficacious and affordable preventive, therapeutic and peri-natal HIV/AIDS vaccines.[45]

Guideline 2.3 of the Vaccine development guidelines states that it is the task of the Kenyan government to 'provide a legal framework for material transfer agreements regarding movement and [the] use of biological specimens'. To date, no legal framework has been promulgated by the Kenyan government. In terms of guideline 4.2, research ethics committees must in their review of proposed vaccine research emphasise the importance that adheres to the storage, disposal and repository of biological materials.

Guideline 7.3, headed 'Informed consent process', describes the procedure for obtaining informed consent from vaccine trial participants to participate in vaccine research. It merely states that no biological material transfer is permitted without the informed consent of the trial participants, without elaboration.

Guideline 8.3 of the Vaccine development guidelines elaborates on the transfer of human biological specimens. The guideline requires that biological material transfer agreements (MTAs) govern all transferred materials and specimens used for vaccine studies. MTAs must state: that the materials or specimens are for scientific, educational and non-commercial purposes only; that 'other use of materials and specimens or research results, including but not limited to commercial development, may proceed only after concluding a co-operative research and development agreement' (RADA). Further, negotiations must be completed and the RADA executed before commercial sale of the products may proceed. A RADA must be binding on all parties with respect to intellectual property rights. And that 'any unauthorized commercial use of the materials and specimens or results without the said agreement will be subject to financial penalty by court of law'. The Vaccine development guidelines declare that no material transfer is allowed without the consent of the trial participant or without approval of the protocol (by a research ethics committee) and in accordance with the

[45] Guideline 1.3 of the Vaccine development guidelines.

Ministry of Health's guidelines on the transfer of biological materials. Appendix 5 of the Vaccine development guidelines provides a sample MTA that may be used by researchers.[46] The sample MTA stipulates the mutually-agreed terms and conditions governing the transfer of biological material, as well as the rights and obligations of both the provider and the recipient of the material.[47]

Guideline 8.3 aims to safeguard Kenyan researchers and Kenyan research participants from exploitation which takes the form of commercial products that are developed without adequate compensation to the research participants who donated the material or biological specimens. Its insistence on a RADA as a prerequisite for the commercial use of materials and specimens underscores this point. However, guideline 8.3 indicates that uses other than commercial development are allowed, as long as a MTA is in place; in other words, biological specimens may be exported for future research.

Significantly, although guideline 8.3 states that research participants must consent to the transfer of biological material, no guidance is given about the form such consent should take. It seems that the participants' consent is merely general; in other words, they need to consent only to the transfer of their specimens and not to the nature of any future reuse of, or research on, such specimens.

The Ministry of Higher Education, Science and Technology of Kenya published in 2009 the Technology and Innovation Bill (the Bill). The Bill has not yet been enacted into law but, amongst other aims, seeks to establish institutions and policy guidelines that 'provide for the promotion of research, science, technology and innovation for national socio-economic development; the generation of advice, harmonization, coordination and dissemination of policies for research, science, technology and innovation; the promotion and co-ordination of technology acquisition, adaptation and the diffusion into national development processes; and the development of mechanisms for the promotion and utilization of innovations in the country'.[48]

Section 13 of Part III of the Bill deals with the authorisation of research, science, technology and innovation activities. The Bill states that any person

46 Vaccine development guidelines at 62–66.
47 Vaccine development guidelines at 62.
48 Introduction of the Science, Technology and Innovation Bill (2009).

intending to undertake any research, science, technology and innovation activity in Kenya must apply 'in the prescribed manner' in that regard to the National Commission for Science, Technology and Innovation established under section 60 of the Bill for 'authorization, in accordance with the provisions of this Act'. Activities which need such authorisation in terms of the Bill include the authority or permission 'to access, handle or transfer or move within, from and into Kenya any specified genetic material or any other sample'.[49] Clearly, this section is intended to prohibit the unauthorised accessing, handling or transfer of genetic or other biological samples within or out of Kenya, although it is not clear what is 'specified genetic material or any other sample' as these are not defined in the definition section of the Bill.[50]

The Bill provides that any research, science, technology and innovation activity in a variety of areas requires the authority, license or permit from the Commission.[51] Included are any activity that involves human subjects or tissue; as well as an activity that requires the importation or export of animal, plant or micro-organisms.[52]

Section 19 prescribes quite severe penalties for the transgression of section 14. Section 19.1 states that any person who without authority granted under section 14(1) accesses, handles or transfers or moves within, into or from Kenya any 'specified genetic or other material shall be guilty of an offence and shall, in addition to any other penalty as may be provided for in this Act or any other written law, have the materials confiscated and be barred from undertaking research, science, technology and innovation activities in the country'. These penalties should dissuade researchers from undertaking activities prohibited by the Bill.

Finally, the government of Kenya has promulgated the HIV and AIDS Prevention and Control Act 14 of 2006 (HIV and AIDS Prevention and Control Act). The HIV and AIDS Prevention and Control Act deals with a wide range of issues which relate to HIV and AIDS education, testing and research. Specifically, no research on any tissue or blood removed from a person may be carried out except '(a) with the written informed consent of that […] person'.[53] Section 39 stipulates that no HIV and AIDS-related

---

49 Section 13.2 of the Science, Technology and Innovation Bill (2009).
50 Section 1 of the Science, Technology and Innovation Bill (2009).
51 Section 14.1 of the Science, Technology and Innovation Bill (2009).
52 Secions 14.1 c) and e).
53 Section 40 of the HIV and AIDS Prevention and Control Act.

human biomedical research may be carried out 'on another person, or on any tissue or blood removed from such person unless such research conforms to the requirements under the Science and Technology Act or any other written law for the time in force'. It is significant that although the consent of the participant is required for research on her tissue and blood, the Act does not require consent to reuse or to the export and future use of tissue or blood.

From the above overview of the regulation of consent to, and authorisation of the export of human biological specimens in Kenya, it may be concluded that, as yet, there is little regulation dealing with these matters. With the exception of the Vaccine development guidelines, there is no provision in the guidelines, Bill or Act for a materials transfer agreement or a research and development agreement to protect the interests of Kenyan researchers or research participants. Moreover, the Vaccine development guidelines are the only regulations which require participant consent to the transfer of human biological specimens without indicating the form or nature of the consent. Nevertheless, in terms of both the Vaccine development guidelines and the Technology and Innovation Bill, the Kenyan government must authorise the export of human biological material.

An empirical study by Simon Langat supports these findings. In an article entitled 'Reuse of samples: Ethical issues encountered by two institutional ethics review committees in Kenya',[54] Langat identifies and describes ethical issues arising out of the storage, reuse and exportation of samples in a developing country such as Kenya. Specifically, Langat examines and details the ethical issues encountered by two RECs in Kenya in this regard: the Kenyatta National Hospital (KNH) and the Kenya Medical Research Institute (KEMRI). Some of Langat's findings merit mention here.

With regard to the reuse of biological samples for future research, he found that a considerable number of studies reviewed by the two RECs involved requests that samples be reused for future research.[55] In collaborative protocols between Kenya and other countries, investigators considered the practices in those countries that had regulated reuse, and used these as a minimum standard.[56] Langat found that most local research protocols, as well as those from countries where not much effort had been put into the regulation of the reuse of samples did not consider reuse as being of ethical

54 S Langat 'Reuse of samples: ethical issues encountered by two institutional ethics review committees in Kenya' (2005) 19 *Bioethics* 537 at 537–549.

55 *Id* at 544.

56 *Ibid*.

significance.[57] This finding concurs with the fact that the regulations discussed above do not mention research participant consent to the reuse of their samples.

With respect to the export of samples for research purposes, importantly, Langat declares that in the case of reuse in foreign countries, researchers in Kenyan research projects often do not inform subjects of this likelihood.[58] With regard to intellectual property rights, Langat's finding is that current practice by Kenyan RECs does not address issues of compensation for subjects. Langat raises concerns of justifiability in those protocols he reviewed in which subjects are informed that they cede all claims to any commercial application.

Langat states that Memoranda of Understanding (MOUs) between institutions taking part in research in Kenya are drawn up without any consideration to the research subjects.[59] He notes that the two Kenyan RECs required no ethical reviews to be undertaken in the collaborating foreign institutions; and that if protocols did mention such clearance, they did not include copies of the clearance documents. There were cases in which memoranda of understanding that existed between institutions were cited as granting the right to export material without reference to the Kenyan REC.[60]

Again supporting my own findings, regarding consent forms and research participants' consent to the reuse of their samples, Langat found that in Kenya, 'informed consent sheets do not indicate any deep reflection on the issues of consent-for-reuse by the investigators'. He speculates that this may be because the 'reuse of samples has attracted the attention of bioethics only recently'.[61] He remarks as follows on the lack of a uniform approach in this regard by research ethics committees: 'Thus far, [RECs] do not set any policy on re-use but take a case-by-case approach. This approach has some weaknesses and needs to be complemented by guidelines and regulations: first, it does not set a basic moral standard to be maintained; second, it tends to rely on international guidelines, which are non-specific and ambiguous.'[62]

---

57 *Ibid*.
58 *Ibid*.
59 *Ibid*.
60 *Ibid*.
61 *Id* at 545.
62 *Ibid*.

Langat concludes that in a majority of cases investigators do not inform research subjects about storage, reuse and export; that the awareness about storage, reuse and exportation of samples among researchers is insufficient in the light of a growing interest in these matters; and that the two Kenyan RECs differ in their requirements of what is needed from foreign collaborative proposals.[63]

South Africa

In the South African case, a number of domestic laws and ethics documents relate to consent to, and authorisation of the export and future use of human biological specimens. Legislation, in the form of chapter 9 of the National Health Act 61 of 2003 (the Act), in future will govern health research in South Africa, in conjunction with several draft regulations published in terms of the Act. Additionally, the provisions of chapter 8 of the National Health Act will regulate the control and use of blood, blood products, tissue and gametes in humans, replacing the Human Tissue Act 65 of 1983. Although the Act was promulgated in 2003, neither chapter 8 nor chapter 9 of the National Health Act, as yet, is in effect (only section 53 of chapter 8 has so far entered into force). Chapters 8 and 9 of the National Health Act are discussed, being of particular relevance; the to-be-repealed Human Tissue Act 65 of 1983 is not, as it is the subject of extensive past academic discussion.[64]

In its present form,[65] chapter 8 of the National Health Act deals with the control of the use of blood, blood products, tissue and gametes in humans. According to section 55, no one may remove tissue, blood, a blood product or gametes from the body of another living person for the purpose referred to in section 56 of the Act unless it is done with the written consent of that

---

63 *Id* at 548–549.

64 See *eg,* M Slabbert & H Oosthuizen 'Commercialisation of human organs for transplantation: a view from South Africa' (2005) 24 *Medicine and Law* at 191–201; M Swanepoel 'A proposed legislative framework for the regulation of aspects pertaining to embryonic stem cell research and therapeutic cloning in South Africa' (2010) 73 *Journal of Contemporary Roman-Dutch Law* 1; MN Slabbert 'Cloning and stem cell research: a critical overview of the present legislative regime in Australia and the way forward' (2003) *Journal of Law and Medicine* 515 at 515–516. The relevant section of the Human Tissue Act is section 18 which reads: 'No tissue, blood or gamete shall be removed or withdrawn from the body of a living person for a purpose referred to in section 19 – (a) except in accordance with the prescribed conditions; and (b) unless written consent thereto has been granted – (i)where such a person is a major, by that person; (ii) where such a person is a minor, by the parents or guardians of that person.'

65 Chapter 8 is at present being redrafted; however, it is yet uncertain when the redrafted version will see the light.

person and in accordance with the 'prescribed conditions'. 'Tissue' is defined in section 1 of the Act to signify 'human tissue, and includes flesh, bone, a gland; an organ, skin, bone marrow or body fluid, but excludes blood or a gamete'. According to section 56(1), the use of such removed tissue, blood, blood product or gametes that have been extracted from a living person is limited to 'such medical or dental purposes as may be prescribed'. And, only a registered medical practitioner or dentist may remove, use or transplant tissue into another person.[66]

Section 62 makes provision for the donation of tissue and other matter derived from deceased persons. According to section 64 of the Act, health research is a legitimate purpose for which the tissue of a deceased person may be donated.[67] Chapter 8 is silent as to what is a legitimate purpose for the use of tissue obtained from a living person, presumably this will be governed by regulations in terms of the Act ('purposes as may be prescribed'). Chapter 8 of the National Health Act does not make special provision for authorisation of, or consent to the export of human biological specimens.

Informed consent to participation in research or experimentation is regulated by chapter 9 the National Health Act[68] in accordance with the directive contained in the South African Constitution.[69] Section 71(1) determines that[70]

> … research or experimentation on a living person may only be conducted in the prescribed manner; and with the *written consent* of the person after he or she has been informed of the *object of the research* or experimentation and any *possible positive or negative consequences* to his or her health.

Although consent to the exportation of human biological specimens is not mentioned, it is possible to infer from section 71(1) that the participant's written consent should cover every aspect of the research endeavour – including the possibility that biological specimens may be exported for future use. Further, because the section declares that the research participant should be informed of the object of the research, section 71(1) may be

---

66 Section 59(1).

67 Section 64(1)(b).

68 Before, informed consent to medical intervention (therapeutic and experimental) was governed by the common law and case law.

69 Section 12(2)(c) Constitution of the Republic of South Africa, 1996.

70 My emphasis. The National Health Act has entered into force in 2006, but ch 9, which deals with issues related to health research, has not yet come into effect as of 31 July 2011. Sections 71(2) and 71(3) govern the participation of minors in health research.

interpreted to mean that the participant should be informed also of the object of any future research to be undertaken regarding her biological specimens.[71] However, chapter 9 does not deal expressly with authorisation of, or consent to the export and future use of human tissue.

In terms of section 68 of the National Health Act, on 1 April 2011 the Minister of Health again[72] published draft regulations, entitled Regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, zygotes and gametes (Draft regulations).[73] In terms of Regulation 2(1), '[n]o person may import or export any tissue or any blood, blood product, cultured cells, stem cells or embryo without a permit issued in terms of these regulations'. To apply for such a permit, the potential importer completes a form provided in Annexure 4 and 5 of the Draft regulations.[74] The Director-General may issue a permit which authorises the import or export of human biological material subject to such conditions as he may determine and if satisfied that the information submitted by the applicant meets the requirements of the Draft regulations.[75] According to draft regulation 3(1), applicants need to show proof in writing that the tissue or gametes for which the export permit is being applied, was or were appropriately donated and that they are to be used 'in terms of the Act'. The Draft regulations detail requirements governing the export, specifically, of whole blood, red cell concentrate, fresh frozen plasma and platelet concentrate, as well as placenta tissue, embryonic or foetal tissue, or embryonic, foetal and umbilical stem cells.[76] Further, a register must be kept by an authorised institution that has imported or exported any biological substance in terms of the regulations.[77] In the case of the export of biological material ('a human substance'), a form showing the particulars of the substance, that of the exporting institution, and the details of the institution to which the substance is being exported is to be completed.[78] The draft

71 Section 71(1) should be read together with ss 6(1) and 7(1) of the Act which discuss the informational or knowledge aspect of informed consent. According to s 6(1), informed consent encompasses knowledge about (s 6(1)(a)–(d)): (a) the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to her best interests; (b) the range of diagnostic procedures and treatment options generally available; (c) the benefits, risks, costs and consequences generally associated with each option; and (d) the user's right to refuse health services and the implications, risks, obligations of such refusal.

72 These draft regulations were originally published in 2007.

73 *Government Gazette* 34159 no 266 1 April 2011.

74 Draft reg 2(2).

75 Draft regs 2(3) and 2(4).

76 Draft regs 4(1) and 4(2).

77 Draft reg 7.

78 Draft regs 7(1)(b) i–vii.

regulations do not refer to the consent of the person from whom the exported material has been obtained; but restrict their remit to the authorisation of export by a government agent.

A set of draft regulations – which governs the general control of human bodies, tissue, blood, blood products and gametes – is of relevance to the issue.[79] Draft regulation 2 prescribes that tissue, blood or gametes may only be removed from a living person if that person (or her parent or guardian) has given written consent thereto. It is assumed that consent refers to consent to the removal of the tissue, blood or gametes, rather than to the specific purpose for which the removed tissue will be used. This lack of a reference may not be an oversight, but be due to the fact that section 56(1) of the National Health Act prescribes that such donated tissue may be used 'for such medical or dental purposes as may be prescribed' only.

A number of codes of ethics govern biomedical research on human participants in South Africa: the Medical Research Council's (MRC)[80] Guidelines on ethics for medical research; the Department of Health's Guidelines for Good practice in the conduct of clinical trials in human participants in South Africa; and – relevant to HIV and AIDS-related research – Ethical considerations for HIV/AIDS clinical and epidemiological research, which also is issued by the Department of Health. Each code is discussed below, specifically as pertains to the consent to, and authorisation of the export of human biological specimens.

MRC Guidelines on ethics for medical research

The MRC Guidelines on ethics for medical research (MRC Guidelines),[81] an important codification of research ethics in South Africa,[82] is issued in terms of section 17(1) and 17(2) of the Medical Research Council Act.[83] The MRC

---

79 Regulations regarding the general control of human bodies, tissue, blood, blood products and gametes Reg 268 *Government Gazette* 34159 1 April 2011.

80 The South African Medical Research Council (MRC) was established in terms of two Acts of Parliament (19 of 1969 and 58 of 1991). Its most important functions were defined as promoting 'the improvement of the health and the quality of life of the population of the Republic and to perform other such functions as may be assigned to the MRC by or under this Act'. Such improvement was to be attained 'through research, development and technology transfer'. See also http://www.mrc.ac.za/history/general.htm.

81 (4rev 2004), previous editions are those of 1977, 1987, and 1993.

82 FW van Oosten 'The law and ethics of information and consent in medical research' (2000) 63 *Journal of Contemporary Roman-Dutch Law* 5 at 7.

83 Act 58 of 1991. Sec 17(1) of the Act determines that the MRC Board must regulate and control research on or experimentation upon humans. Section 17(2) empowers the Board to determine ethical directives to be followed in research and experimentation,

Guidelines govern all research carried out by or on behalf of the MRC, as well as research funded by the MRC and approved by its ethics committee.[84] Van Oosten is of the opinion that the MRC Guidelines are to be followed by other research institutions, if that particular body does not have its own ethical guidelines.[85]

The revised series of Guidelines has been divided into five books:[86] Book 1, entitled Guidelines on Ethics for Medical Research: General Principles; Book 2, entitled Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research; Book 3, entitled Guidelines on Ethics for Medical Research: Use of Animals in Research; Book 4, entitled Guidelines on Ethics for Medical Research: Use of Biohazards and Radiation; and, Book 5, Guidelines on Ethics for Medical Research: HIV Vaccine Trials.[87]

Book 1 of the MRC Guidelines sets out the reasons for the revised publication. Its Preface stresses that in the 4th edition, the MRC Ethics Committee has directed that the guidelines must have a South African emphasis, as well, they highlighted the importance of safeguarding the dignity of the individual and of informed consent, which has been entrenched in the Bill of Rights.[88] The argument that developing communities must not be exploited and the view that participating communities must benefit from research done on or with them are foregrounded.[89]

Book 1 of the MRC Guidelines consists of twelve guidelines and deals with such issues as the medical justification for research;[90] the legal and moral justification for research (which includes an extensive section on consent);[91] and the way in which research ought to be conducted.[92] Thus, it includes a

---

and to take the necessary steps to enforce the ethical directives.

84 Van Oosten n 82 above at 7.

85 *Id* at 9. He bases his opinion on the fact that the MRC is a national research institution and the fact that the MRC Guidelines have statutory authority.

86 The reason for splitting the previous single volume into five sections is explained in the Foreword the Book 1 – five different editions will make the task of future revising and updating the Guidelines considerably easier. Also, researchers with specific interests will be able to access a single volume that relates to their interests.

87 Neither Book 2, entitled Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research, nor Book 5, entitled, Guidelines on Ethics for Medical Research: HIV Vaccine Trials, contain any special mention of consent to and authorisation for export and future use of biological specimens.

88 MRC guidelines 5.

89 *Ibid*.

90 Guideline 4.

91 Guideline 5.

92 Guideline 6.

large section on research participants;[93] ethical issues in qualitative research;[94] the assessment of ethics in research;[95] the monitoring of research;[96] international collaboration in research;[97] and, ethical guidelines for epidemiology.[98]

Guideline 11, which deals with international collaborative research, is of special relevance to the present discussion. Guideline 11.4.2, entitled 'Exploitation', prohibits exploitation of institutions, investigators, research participants or communities,[99] but is unclear as to which actions amount to exploitation.[100] The MRC guidelines insist that before research commences the intellectual property rights of institutions, investigators, participants and communities be acknowledged, respected and shared[101] and that there is an equitable compensation of institutions, investigators, participants and communities (this compensation is to go beyond financial compensation);[102] and stress that sponsors and investigators have a moral obligation to assist indigenous peoples, traditional societies and local communities in the protection of their knowledge and resources as well as of that which is sacred and secret by tradition.[103]

The MRC guidelines stress that the community in which the research is undertaken should benefit from research; including benefits from multi-centre clinical trials. For example, by gaining access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study. Moreover, collaborative research should be of benefit to the host country,[104] such as through the development of the host country's health or research infrastructure or research capacity.[105]

Although the unauthorised export and future use of research participants' biological specimens without their consent certainly amounts to exploitation in terms of the guidelines, they make no explicit reference to the issue.

---

93 Guideline 7.
94 Guideline 8.
95 Guideline 9.
96 Guideline 10.
97 Guideline 11.
98 Guideline 12.
99 Guideline 11.4.2 i.
100 See also para 2 above.
101 Guideline 11.4.2 MRC guidelines.
102 Guideline 11.4.2 MRC guidelines.
103 Guideline 11.4.2 MRC guidelines.
104 Guideline 11.4.4 MRC guidelines; gl 7 Good Practice guidelines.
105 Guideline 11.4.4 MRC guidelines; gl 7 Good Practice guidelines.

Guidelines for good practice in the conduct of clinical trials on human participants in South Africa

The Department of Health issued the Guidelines for Good practice in the conduct of clinical trials in human participants in South Africa (Good practice guidelines) in September 2000. The Preamble to the Good practice guidelines states that the aim is to provide 'South Africa with clearly articulated standards of good clinical practice in research that are also relevant to local realities and contexts'.[106] The Good practice guidelines apparently are applicable to both academic and contract research in South Africa but, unlike the MRC Guidelines that are issued in accordance with a statute, they have no statutory basis.[107]

The Good practice guidelines are divided into nine chapters. The introduction discusses the reasons for and scope of the guidelines and is followed by an explanation of the role of bodies such as the ethics committee during ethical review, which in turn, leads to an examination of the protection offered study participants;[108] the responsibility of the principle investigator and participating investigators;[109] the responsibilities of the sponsor[110] and quality assurance;[111] as well as issues such as data management and statistics,[112] multi-centre studies[113] and ethics committees.[114] But the Guidelines do not refer specifically to authorisation of, or consent to the export and future use of human biological specimens.

Although authorisation to export human biological material is addressed adequately by the Draft regulations in terms of the National Health Act, from the above overview of the regulation of consent to, and authorisation of the export of human biological specimens in South Africa, it appears that no provision is made for individual research participant consent to the export and future use of their biological specimens in the law, or in its draft regulations or in the ethics guidelines.

---

106 Preamble, Good practice guidelines.
107 See above.
108 Guideline 2.
109 Guideline 3.
110 Guideline 4.
111 Guideline 5.
112 Guideline 6.
113 Guideline 7.
114 Guideline 8.

CONCLUSIONS DRAWN FROM A COMPARATIVE STUDY

Of the countries under investigation and, judging solely on provisions contained in legislation and the ethical guidelines, the Nigerian and Kenyan authorities seem most aware of potential exploitation by foreign researchers through the export of human biological specimens, and of their responsibility in protecting research participants from exploitation. This awareness is shown, for example, by the requirement of a materials transfer agreement when biological specimens are exported. South African legislation and ethical guidelines do not refer to a materials transfer agreement or a research and development agreement which protects the interests of South African researchers and research participants.

In all three countries there is to be authorisation by a government agency for the export of human biological specimens. In Nigeria the National Code of Health Research Ethics nominates the HREC as the agency that is empowered to provide authorisation upon the receipt of a materials transfer agreement that meets requirements; in Kenya, in terms of both the Vaccine development guidelines and the Technology and Innovation Bill, the Kenyan government authorises the export of human biological material; and in South Africa, the issue is addressed by the draft Regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, zygotes and gametes in terms of the National Health Act which directs that the Director-General in the Department of Health authorises the export of human biological specimens.

Significantly, none of the examples illustrates a comprehensive appreciation of the importance in obtaining the informed consent of individual research participants to the export and future use of their biological specimens. In Nigeria, although individual RECs have a duty to ensure that in exporting human biological specimens, the material transfer agreements correspond to the contents of the informed consent documents signed by research participants, these regulations are silent on the nature or formalities required for the informed consent of the research participants from whom the biological samples are obtained. In Kenya, the Vaccine development guidelines are the sole regulations which raise participant consent to the transfer of human biological specimens, yet they do not indicate the form or nature of such consent, for example, in guideline 8.3 which states that research participants must consent to the transfer of biological material. It appears that consent is merely general, in other words, participants need to consent to the transfer of their specimens and not specifically to the nature of any future reuse of or research on such specimens. In South Africa there

is no provision in place for individual research participant consent to the export and future use of their biological specimens in the National Health Act, its draft regulations or the ethical guidelines.

South Africa, therefore, offers least protection to researchers and research participants from exploitation in the export and future use of their biological specimens. Generally, South Africa is regarded as having advanced protections measures for research participants, yet, in the area of protecting research participants against the unauthorised export and use of their biological material, South African research participants are not better off than their counterparts in the rest of Africa.

Because of the lack of attention given to research participant consent in the three countries under discussion, research participants in these countries, at best, are considered to have given implied *general* consent or broad consent to the export and future use of their biological specimens. Through an implied general consent, the participant either has or is deemed to have consented to the export and future use of her samples for any research project at any future point in time. In effect, the research participant has lost control over the future use of her biological specimens.

Briefly, at this point attention is given to the role of research ethics committees in this regard.

ROLE OF RESEARCH ETHICS COMMITTEES

The 1970s witnessed the birth of the research ethics committee (REC), or, as it is called in many countries, the institutional review board.[115] RECs are set up to oversee the ethical conduct of clinical research and are the primary mechanisms by which to protect the interests of research participants. Lisa Eckenwiler writes as follows about the role of RECs:[116]

> Institutional review boards (IRBs) represent a particular approach to answering to people – the public generally, research participants more directly – in terms of responsibilities that have come to be recognised within the research community. Their efforts, indeed, can be understood as a special case of an important move made in moral life: reasoning about the interests of others in coming to conclusions about what is ethically acceptable.

---

115 Often abbreviated as IRB.

116 L Eckenwiler 'Moral reasoning and the review of research involving human subjects' (2001) 11 *Kennedy Institute of Ethics Journal* 37 at 37.

In the countries under investigation, the independent ethical review of proposed research by a REC is provided for in legislation. Generally, RECs are to:[117]

> maintain ethical standards of practice in research;
> protect research participants and investigators from harm or exploitation;
> preserve the research participant's rights over society's rights; and
> provide reassurance to society that these roles are carried out.

Research ethics committees exist in academic and other institutions where clinical research is conducted. For instance, the medical faculties of universities in different countries each has its own research ethics committee. In line with the duties of RECs outlined above, it is the primary responsibility of RECs to ensure that the appropriate consent to, and authorisation for the export of human biological specimens is obtained from research participants.

However, as the study by Langat shows,[118] because the issue only recently has engaged the interest of bioethicists, in Kenya most local and foreign research protocols serving before RECs do not indicate that significance attaches to the export and future use of biological specimens.[119] An equivalent study has not been undertaken in either of the other countries. Consequently, there is scant information on the attitude of RECs in this regard. Nonetheless, generally studies indicate that members of RECs in Africa feel that they lack the capacity to adequately evaluate the ethical implications and scientific design (including risks and benefits) of proposed clinical studies.[120] Given this perceived lack of capacity, together with a dearth of adequate regulation on the matter, it is assumed that hitherto little attention has been paid by RECs in Africa to the rights and interests of research participants and researchers regarding consent to, and authorisation of the export and future use of human biological specimens.

---

117 Guideline 6.1.9 MRC guidelines (South Africa).

118 Langat n 54 above at 537–549.

119 *Ibid*.

120 See *eg* A Nyika *et al* 'Composition, training needs and independence of ethics review committees across Africa: Are the gate-keepers rising to the emerging challenges' (2009) 35 *Journal of Medical Ethics* 189 at 190; L Moodley & L Myer 'Health Research Ethics Committees in South Africa 12 years into democracy' (2007) 8 *Medical Ethics* 1; JKB Ikingurai, M Kruger &d W Zeleke 'Health research ethics review and needs of institutional ethics committees in Tanzania' (2007) 9 *Tanzania Health Research Bulletin* 154 at 155–157.

CONCLUSION

The charge has been levelled that international researchers 'change their ethics at the customs desk' when arriving in Africa or other parts of the developing world.[121] The comparative study undertaken by this article demonstrates that in the case of participant consent to the export and future use of human biological specimens for research, at least with regard to these countries, they are themselves responsible for the potential exploitation of research participants as measures to protect African researchers and research participants are lacking. Notably, with reference to the informed consent of research participants, existing regulations fail to describe the requirements for, extent of, or form of research participant consent to the export and future use of their biological specimens.

The argument that biological specimens lose their ethical significance as soon as identifiers which may link them to individual research participants are removed does not stand up to investigation and has long ago been refuted.[122] Internationally, there is a heightened understanding that biological specimens have ethical significance, and are potentially scientifically and commercially valuable.[123] Meslin and Quaid write: 'Now that the human genome has been sequenced, the future of medicine will depend largely on the ability of investigators to gain access to large quantities of HBMs [human biological materials].'[124]

In light of the above, the conclusion supports the following recommendations. First, developing country governments need urgently to establish the ethical and legal frameworks necessary outlining the conditions under which and the processes by which, human biological specimens may be exported for future research. Materials transfer and co-operative research and development agreements are required to safeguard the interests of developing-country scientists and research participants. The practice followed in India serves as a model.[125] The Indian Guidelines for exchange of human biological material for biomedical research purposes (Indian guidelines), specify that the transfer of 'human materials should be an integral part of a collaborative project, which should have been approved by

---

121 Geller *et al* n 12 above at 268.

122 Langat n 54 above at 539 and 549.

123 EM Meslin & KA Quaid 'Ethical issues in the collection, storage, and research use of human biological materials' (2004) 144 *Journal of Laboratory and Clinical Medicine* 229 at 229.

124 *Ibid*.

125 F No L 19015/53/97–IH(Pt) Government of India Ministry of Health & FW Department of Health, Nirman Bhawan, New Delhi (19 November 1997).

the Institutional Review and Ethics committees, and not be a separate activity';[126] and that, 'to protect the rights of the Indian study subjects as well as Indian scientists/organisations, Memoranda of Understanding and/or Agreements on Material Transfer should be entered into between the collaborating partners (Indian and foreign)'.[127]

Second, in keeping with the core ethical value of respect for persons, researchers should be compelled to obtain and clearly document research participants' informed consent to the exportation and possible future use of their biological specimens. Consent must be explicit and may take any of the forms used in international regulations as summarised by Salvaterra *et al*:[128]

> Broad consent which allows the use of biological specimens and related data in immediate research and in future investigations of any kind at any time;
> Partially restricted consent which allows the use of biological specimens and related data in specific immediate research and in future investigations directly or indirectly associated with them;
> Specific informed consent which allows the use of biological specimens and related data only in immediate research; forbids any future study that is not foreseen at the time of the original consent; and
> Multi-layered consent which requires several options to be explained to the research subject in a detailed form.[129]

In some projects, especially those in which the specimens of an entire community are obtained for future research, community engagement and community consent is a basic requirement and coincides with Anton van Niekerk's view that 'it is also problematic to simply apply Western standards of informed consent to indigenous Africans. The African's idea of personhood is much less related to Western ideas of individual autonomy, and is much more closely related to family ties and community-based'.[130] Community engagement and community consent are especially important in

---

126 Guideline II (iii) Indian guidelines.

127 Guideline II (iv) Indian guidelines.

128 Salvaterra *et al* n 9 above at 309. The World Health Organization, for example, in its Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells and Fluids in Research (2003) requires either specific informed consent or partially restricted consent.

129 Multi-layered consent would require the research participant to choose an option ranging from broad consent to specific informed consent.

130 AA van Niekerk 'Mother-to-child-transmission of HIV/AIDS in Africa: ethical problems and perspectives' at 11, available at: http://0-sun025.sun.ac.za.innopac.up.ac.za/portal/page/portal/Arts/Departments/philosophy/cae/doc_pubs/Tab/Van%20Niekerk%20on%20MTCT.pdf.

instances where research is done on the biological specimens of entire communities in which there is a particular genetic variation.[131]

Third, there is an urgent need for African research ethics committees to be trained in the review of research protocols which involve the export of, and future research on human biological specimens. The primary responsibility of RECs is the protection of research participants, but members of RECs cannot perform this function if they lack the capacity to assess ethical and legal issues relating to the export and future use in research of human biological specimens.

To conclude, in the spirit of UNESCO's Universal Declaration on the Human Genome and Human Rights,[132] article 10 of which states:

> No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.

---

131 See, *eg*, B Godarda, J Marshallb &C Labergec 'Community engagement in genetic research: results of the first public consultation for the Quebec CARTaGENE Project' (2007) 3 *Community Genetics* 147 at 147–148.

132 The Universal Declaration on the Human Genome and Human Rights was adopted unanimously and by acclamation at UNESCO's 29th General Conference on 11 November 1997. The following year the United Nations General Assembly endorsed the Declaration; available from http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genome-and-human-rights/.