# *Human Biobanking in Developed and Developing Countries: An Ethico-Legal Comparative Analysis of the Frameworks in the United Kingdom, Australia, Uganda, and South Africa*

SAFIA MAHOMED

**Abstract:** Although the concept of biobanking is not new, the open and evolving nature of biobanks has created profound ethical, legal, and social implications, including issues around informed consent, community engagement, secondary uses of materials over time, ownership of materials, data sharing, and privacy. Complexities also emerge because of increasing international collaborations and differing national positions. In addition, the degrees and topics of concern vary as legislative, ethical, and social frameworks differ across developed and developing countries. Implementing national laws in an internationally consistent manner is also problematic. However, these concerns should not cause countries, especially developing countries, to lag behind as this novel wave of research gains momentum, particularly while several biobank initiatives are already underway in the developing world. As the law has always struggled to keep up with the fast-evolving scientific arena, this article seeks to identify the ethico-legal frameworks in place in the United Kingdom, Australia, Uganda, and South Africa, for human biobank research, in an attempt to compare and contextualize the approaches to human biobanking in specific developed and developing countries.

**Keywords:** human biobanking; developing and developed countries; secondary uses of materials; ownership; privacy; community engagement; informed consent; broad consent; ethico-legal framework

## Introduction

There is currently no uniform and universally accepted definition for human biobanks and genetic research databases. However, a general definition of these is offered by the Organization for Economic Co-operation and Development (OECD) guidelines. According to the OECD guidelines, a human biobank and genetic research database are:

> structured resources that can be used for the purpose of genetic research and which include: (a) human biological materials and/or information generated from the analysis of same; and (b) extensive associated information.[1]

It therefore appears that the terms "biobank" and "genetic research database" are used interchangeably. The difference between conventional and biobank research

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is that conventional research involves the use of samples in specific and defined ways, whereas biobank research typically involves the extensive networking of samples, the exact uses of which, cannot always be identified during the initial research process. Although the concept of biobanking is not new, the open and evolving nature of biobanks has created profound ethical, legal, and social implications, including issues around informed consent, community engagement, secondary uses of materials over time, ownership of materials, data sharing, and privacy. Complexities also emerge because of increasing international collaborations and differing national positions. In addition, the degree and areas of concern vary as legislative, ethical, and social frameworks differ across developed and developing countries.[2]

This article seeks to identify the ethico-legal frameworks in place in the United Kingdom, Australia, Uganda, and South Africa, for human biobank research, in an attempt to compare and contextualize the approaches to human biobanking in specific developed and developing countries. The reason that these four countries have been selected for comparison are because as former colonies of the British Empire, the Australian, Ugandan, and South African legal systems may be described as multilayered, incorporating many similarities to the legislative system adopted in the United Kingdom,[3] which is often described as a frontrunner with regard to medical research. It will therefore be practical to observe specific established systems based on Western influences and ideals and compare these to two developing African frameworks, which have their roots grounded in fairly young democracies. An analysis of the ethico-legal frameworks of each country will now follow, in order to offer a background context with regard to human biobank research.

## United Kingdom (UK)

### *Ethico-Legal Framework and Governance Structures Relevant to Biobank Research*

The UK played a leading role in the Human Genome Project and, at a country level, dedicated specific funding to capitalize on genomic progress.[4] In 2005, a national, population-scale biobank (i.e., the national UK Biobank) was established to advance health research by collecting a wide range of clinical and medical information from participants, with sample storage reaching, approximately, 14 million samples.[5] Apart from the national population-scale UK Biobank, there are several other biobanks, including small-scale biobanks; university research biobanks; clinic-based biobanks; and specific disease–focused biobanks which operate within the UK.[6] Needless to say, with several biobank projects currently underway, and a national population-scale biobank, which supports the investigation into a wide range of diseases occurring in the local population, the UK is a developed country at the forefront of biobank research in Europe.

Interestingly, the UK is one of a few countries in the world that does not have a written Constitution. An accumulation of various statutes, conventions, judicial decisions, and treaties may collectively be referred to as the "British Constitution." The fact that the Constitution is not written down in one codified document may be attributed to the UK's history as a nation and colonialist state. Unlike other countries that have experienced regime change or revolution and have had to develop their legal principle structures at a foundational level, the UK legal

framework, in its entirety, has evolved over a long period of time with relative stability.[7]

In the UK, there is no specific legislation related to biobank research[8]; however, this does not mean that biobanks operate in a completely unregulated terrain. Differing acts, policies, regulations, common law doctrines, codes of practice, conventions, declarations, and recommendations apply in terms of their relevance to a specific scenario.[9] The UK is also currently subject to European Directives and Regulations as a European Union member state, which may change in future, following the UK's vote to leave the EU. In the interim, the interpretation of EU laws will still have an influence on the UK legal system until the finalization of formalized processes to exit the EU are enforced.[10]

As there is no specific legislation directly applicable to biobank research, certain funding bodies, such as the Medical Research Council and the Wellcome Trust Charity, have created their own guidance documents or codes of practice, compliance with which, although not binding under UK law, (in most instances) forms the minimum standard in order to receive funding.[11] Before 2011, there was no singular body responsible for the oversight of research processes in the UK. However, this position changed with the establishment of the Human Research Authority[12] (HRA) whose main purpose is to protect and promote the interests of patients and the public in health and social care research.

According to the HRA Standard Operating Procedures (SOPs), ethical approval is required to store or use the tissue of living or deceased person(s) for a research project or to export the tissue of a living person in the event that no consent was provided for further use of the tissues.[13] It is prudent to note at this juncture that Research Ethics Committee's (REC) approval is only legally required where the activities of a research database would include accessing or otherwise processing the identifiable data of patients or service users, outside their normal care team, without consent.[14] Therefore, applications for ethical review of research databases are normally made on a voluntary basis.[15] According to the SOP, a research database means: "A structured collection of individual-level personal information, which is stored for potential research purposes beyond the life of a specific research project with defined endpoints."[16] Ethical approval will allow the research database team to collect, store, and use identifiable data for the purposes for which consent has been sought.[17]

UK Biobank, the Wellcome Trust, and the Medical Research Council (UK Biobank funders) established their own internal ethical and governance framework to ensure that management of the national biobank is in the public's best interests. This framework has been acclaimed as an example of state-of-the-art biobank governance.[18] Although this ethical and governance framework is not legally binding, UK Biobank would suffer irreversible damage in the event of a breach, which could eventually lead to public distrust in the national biobank, widespread participant withdrawal, and ultimate closure. In order to maintain public trust, effective mechanisms to protect participant autonomy and privacy must be in place. The Australian position with regard to the ethico-legal framework applicable to biobank research will now be analyzed.

## Australia

### *Ethico-Legal Framework and Governance Structures Relevant to Biobank Research*

Australia, similar to the UK, is also considered a leading country in respect of health research. The Australian Government and state and territory governments provide funding for and support a variety of other health services, including population health programs, health and medical research, and health infrastructure.[19] Australia holds a leading position with regard to medical and health research,[20] and about one quarter of health research occurs within the private sector. The National Health and Medical Research Council (NHMRC) is Australia's leading funding body, promoting the development and maintenance of public and individual health standards and supporting a wide range of health research areas including biobank research.[21] There are many ongoing biobanking projects, entities, and activities underway in Australia.[22] However, they effectively operate independently of one another, with each biobank having its own internal processes to manage the collection, storage, and transfer of samples and data. It may be argued that functioning in this autonomous manner has caused a lack of standardization and a duplication of efforts and infrastructures.[23]

As a former British colony, Australia mirrors a number of elements from the British legal system. The Constitution of Australia is the supreme law under which the government operates. The National Health Act 1953 provides for health services and regulates national health services.[24] The Australian Code for the Responsible Conduct of Research[25] sets out the general principles for conducting responsible research. The NHMRC has also been active in developing detailed policy and guidelines specific to health research (and more recently biobank research) in this regard. For the first time, in 2007, the NHMRC included a section on biobanks in the National Statement on Ethical Conduct in Human Research[26] (the National Statement) which advocates for the ethical review of a biobank and Human Research Ethics Committee (HREC) approval for the collection, processing, storage, consent, transfer, and disposal of biospecimens collected for research purposes.[27]

In 2010, the NHMRC issued an Information Paper on Biobanks which provides for relevant information on the establishment, management, and governance of biobanks in Australia.[28] In 2011, the Department of Industry, Innovation, Science and Research published a Strategic Roadmap for Australian Research Infrastructure, which specifically outlines the significant impact biobanking has in the health research context,[29] and in 2012, the NHMRC released a National Biobank Strategy report which sets out the strategic objectives, advantages, and principles of establishing a national approach to biobanking.[30] Most biobanks in Australia are members of the Australasian Biospecimen Network (ABN), which has a recognized set of guiding principles, the ABN Network Biorepository Protocols.[31] This protocol outlines issues related to consent, privacy, access, processing, storage, collection, and data management among other principles. It also provides templates useful for consent.

Research that is of a "negligible risk"[32] (where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience) and involves the use of existing collections of data or records that contain nonidentifiable data is exempt from ethical review.[33] Although Australia does not have specific legislation

which addresses the concerns of biobank research, it does (through the NHMRC) have concise policy in this regard. The positions with regard to the regulatory frameworks of two developed countries, in respect of biobank research, have been outlined. The positions in Uganda and South Africa, whose social and economic structures vary significantly from that of the UK and Australia, will now be discussed.

## Uganda

### *Ethico-Legal Framework and Governance Structures Relevant to Biobank Research*

African populations in general tend to struggle with extreme poverty and harbor the bulk of the disease burden globally.[34] Their populations also often form "participant bases" in the context of cross-border health research. It is therefore reasonable to assume that developing countries, such as Uganda and South Africa, should be involved in progressive health research projects that would ultimately lead to improving their healthcare systems. However, unlike the UK and Australia, government funding in Uganda and South Africa (in Africa in general) and long-term sustainability of research projects remain a serious problem.[35] Research tends to be sponsored from outside sources rather than being embraced as a national responsibility. This presents additional challenges as international collaborations in developing countries raise their own unique set of concerns.[36]

With regard to biobanking, Uganda has not lagged behind as genomic research offers the promise of hope to a nation struggling with an increasing disease burden and growing stigma associated with specific diseases.[37] The Integrated Biorepository of H3Africa Uganda, (IBRH3AU) is the most well-known biobank in the country. The H3Africa Initiative aims to facilitate the study of genomics and environmental determinants, in order to improve the health of African populations.[38] In addition, the Ugandan Medical Informatics Centre (UMIC)[39] has the potential to collect, store, and analyze data for genomic research purposes.

Most developing countries' ethico-legal systems are influenced by developed jurisdictions, in particular European countries and the United States.[40] One reason may be that funding for health research predominantly originates from organizations based in the Western world. However, developed world systems may not always work in developing countries where tradition and culture play a big part in determining an individual's or community's perception to and/or participation in research. The Constitution of Uganda[41] provides that the State shall take all practical measures to ensure the provision of basic medical services to the population; however, it remains silent on research. The Public Health Act[42] is also completely silent on any aspect related to health research. The National Guidelines for Research Involving Humans as Research Participants,[43] ("National Guidelines") developed by the National Council for Science and Technology,[44] appears to be the only document which regulates health research in Uganda. The National Guidelines provide mechanisms for protecting the rights and welfare of research participants, provide ethical standards and procedures for the conduct of research involving humans as research participants, and ensure that researchers take into account social and cultural values of participating communities.[45]

The reach of the National Guidelines is quite broad and aims to apply both nationally and internationally, when human materials from Uganda are collected

for research purposes and transferred across borders. The oversight functions of research involving human participants lie with RECs (at an organizational level) and the Uganda National Council for Science and Technology (UNCST), in collaboration with the Ugandan National Health Research Organisation (UNHRO) for health research (at a national level).[46] The National Guidelines provide various protections to research participants,[47] significantly including that research should be conducted in a manner that does not violate the rights and welfare of participants *and their communities*. The concept of "community welfare" is not a concept that has been identified as a requirement for research in the UK and Australia. Although, in Australia, there is recognition of respect for different cultural values, this does not extend as far as ensuring that community rights and the welfare of the community are not violated, where health research is concerned.

Of note, with respect to RECs, their role does not stop at the time the protocol is approved but is rather a continuing function. This is an additional important safeguard in order to monitor approved studies.[48] The section that follows establishes what the South African ethico-legal framework outlines in respect of biobank research.

## South Africa

### *Ethico-Legal Framework and Governance Structures Relevant to Biobank Research*

Health research is conducted on a large scale in South Africa, with a particular focus on the human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS) epidemic.[49] Although there is no national biobank in the country, there are several institutional- and project-based biobanks which currently operate in South Africa through sponsored initiatives, for example, the H3Africa biobank initiative. South Africa's colonized past, similar to that of Uganda, has had a unique influence on its current mixed legal system, which incorporates many characteristics of the UK's legal model.[50] In South Africa, the Constitution of the Republic of South Africa, 1996, is the supreme law of the country. It forms the apex to the legislative framework in that no other law or government action supersedes its provisions.[51] Following its Constitution, South Africa's legal framework consists of various legislation. The National Health Act 61 of 2003 sets out foundational principles for the regulation of healthcare in the country. However, South Africa's laws are completely silent with regard to biobank research. Nevertheless, it does have National Ethics Guidelines,[52] which were revised in 2015, to include aspects of biobank research. The current National Ethics Guidelines is the only document which attempts to define and regulate biobank research in South Africa. The Guidelines do provide for appropriate safeguards, including physical, administrative, and technical, to protect against unauthorized handling of materials or data and require that new repositories be approved by a REC.

It is evident that none of the above analyzed countries has laws specific to biobanking. One reason for this may be that many different issues relate to biobank research; therefore, one piece of legislation in this regard may be impractical to implement. Another reason may be that the law has always struggled to keep up with the fast-evolving scientific arena. In most instances, biobank research is predominantly regulated by ethical guidelines. However, there is still a large gap between legislative documents with legal status and ethical guidelines.

Furthermore, it is difficult to compel objectors to the ethical guidelines to comply with these. Nevertheless, in the context of health research, acting contrary to ethical guidelines may lead to unprofessional conduct, or professional misconduct, which could in turn present a legal challenge. Therefore, the status of ethical guidelines, specifically in the healthcare setting, should not be reduced or diminished.

I will now analyze how each country regulates biobank research with specific regard to informed consent, ownership, import and export, and community engagement. A brief summary of each country position is provided in the table below:

## Comparative Analysis

From the above Table, it is evident that all analyzed countries require ethical approval for biobank research and view broad consent/broad informed consent as an acceptable informed consent model. Broad informed consent is explained by the International Ethical Guidelines for Health-related Research Involving Humans, prepared by the Council for International Organizations of Medical Sciences in collaboration with the World Health Organization[53] (CIOMS guidelines) as follows:

> Broad informed consent encompasses the range of future uses in research for which consent is given. Broad informed consent is not blanket consent that would allow future use of bodily material without any restriction. On the contrary, broad informed consent places certain limitations on the future use of bodily materials. Broad informed consent forms should specify the purpose of the biobank; the conditions and duration of storage; the rules of access to the biobank; the ways in which the donor can contact the biobank custodian and remain informed about future use; the foreseeable uses of the materials, whether limited to an already fully defined study or extending to a number of wholly or partially undefined studies; the intended goal of such use, whether only for basic or applied research, or also for commercial purposes; and the possibility of unsolicited findings and how they will be dealt with. The research ethics committee must ensure that the proposed collections, the storage protocol, and the consent procedure meet these specifications.[54]

Therefore, broad consent appears to be a preferred method of consent for biobank research in both the developed and developing world.

The general rule regarding ownership of human materials is that participants relinquish ownership rights in their samples once they have donated these for research purposes. This is certainly the case in the UK and Australia. However, in Australia, the general position is that the biobank is a custodian (guardian) of the materials rather than a legal owner. Compared to the South African situation that remains unsettled and nonspecific, Uganda specifically outlines that ownership vests with the participant, although the biobank remains a custodian of the materials and in a position of trust. In addition, according its national Material Transfer Agreement (MTA) template, if an outside organization discovers a new product from the use of human materials which have been sourced from Uganda, and if no stipulation as to ownership is included in the MTA, then the provider institute based in Uganda can automatically lay claim to ownership of the new discovered product.[55] This is a bold step by Uganda, which could be considered

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**Comparative Analysis—UK, Australian, Ugandan, and South African Systems**

| Country | Legislation specific to biobanking | Approvals | Consent model | Ownership | Import/export | Community engagement | Privacy safeguards |
|---|---|---|---|---|---|---|---|
| United Kingdom | No formal law<br>HRA guidelines apply | HTA license required<br>Biobank and REC approval | Broad consent | Participants do not retain ownership<br>Ownership transferred to biobank | Import: HTA license desirable<br>Export: No legal requirement for licensing or ethical approval<br>MTA required by UK Biobank | Not specified | Data require security measures<br>Pseudonymization/ coded |
| Australia | No formal law<br>NHMRC guidelines apply | HREC approval | Growing support for broad consent | Remains unsettled<br>General position: Participant relinquishes ownership<br>Entity = custodian | Import: Biospecimens must be obtained in a manner consistent with the Australian framework<br>Export: Ethical approval required<br>MTA = best practice | Specifies community involvement | Data require security measures<br>Samples are generally coded |
| Uganda | No formal law<br>UNCST | Two pronged: First, REC approval | Broad consent | Ownership remains | Import: Clearance from UNCST | Specified in detail | General data protection Non-specific |

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| Country | Legislation specific to biobanking | Approvals | Consent model | Ownership | Import/export | Community engagement | Privacy safeguards |
|---|---|---|---|---|---|---|---|
| | guidelines apply | (organization level<br>Second, UNCST in collaboration with UNHRO approval (national level) | | with the participant<br>Entity = Custodian | for cross-border transfers<br>Export: Clearance from UNCST<br>MTA required by national guidelines | | |
| South Africa | No formal law National ethics guidelines apply | REC approval | Different forms of consent, including broad consent are implicated | Unsettled General position: No one (including an entity) has ownership rights | Import and export: Permit required MTA required by ethical guidelines | Mentioned generally | General data protection Non-specific Usually coded or anonymous data |

contrary to internationally accepted practices regarding intellectual property rights and patents in new discoveries.

With regard to the import and export of human materials in the UK, it is desirable for imported tissues to be stored in an entity that has a Human Tissue Authority (HTA) license. If the entity does not have an HTA license, each research project using the tissue will require National Health Service (NHS) REC approval.[56] With regard to export, there is no legal requirement for licensing or ethical approval, yet, voluntary applications for approval may be made to an NHS REC. The Australian position holds that there is an onus on the researcher to establish whether the biospecimens were obtained in a manner consistent with the requirements of the National Statement and other relevant Australian legislation when importing samples. If it cannot be established that the biospecimens were obtained in a manner consistent with the requirements of the National Statement and other relevant Australian legislation, then they should not be used for research purposes. Exporting samples for research is allowed in Australia provided that there is ethical approval or that the exportation of the biospecimens is consistent with the original consent and ethical approval is provided by a HREC.[57]

In Uganda, importing materials requires clearance from the UNCST, except for the exchange of human materials between organizations within the country. In respect of exporting materials, clearance from UNCST must be obtained and an MTA must be in place. It is important to note that human materials cannot be transferred outside Uganda, unless it is demonstrated that in-country capacity to perform certain types of investigations/testing does not exist or is inadequate.[58] This requirement is similar to the positions in Botswana and Kenya.[59] In South Africa, the import and export of human materials is governed by the Regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, foetal tissue, zygotes, and gametes.[60] The National Ethics Guidelines published in 2015 are silent on the processes regarding importing or exporting human material. According to the Regulations, a permit issued by the Department of Health is required before any human material may be imported or exported.

With regard to community engagement, the UK guidelines are silent. The Australian guidelines specify community involvement under specific circumstances,[61] and the Ugandan framework outlines a detailed process with regard to community engagement.[62] The South African guidelines mention community engagement in a very general manner with no specific direction in terms of process.

All countries provide that adequate measures should be in place to ensure privacy and confidentiality of participant samples and data. However, although the UK and Australia specify that data should be coded,[63] the South African framework provides different options of data security methods but leaves the determination of "risk" up to an individual REC. The Ugandan guidelines do not provide for methods of data protection and remain unspecific. This could be considered as an area of the National Guidelines which requires improvement.

## Conclusion

In light of the above comparison, it is evident that broad consent as a model is being embraced by different countries with varying social and economic backgrounds. Adequate governance of the biobank and oversight of research projects are a

fundamental concept that cannot be overlooked, and suitable methods to protect the privacy of participant information are paramount. These principles resonate with recently published international guidelines.[64] It is also apparent that because the reach of biobank research penetrates into different aspects of a nation's legislative framework, adopting a singular Act, may not be the most appropriate method of regulating this terrain. A Report by the Bioethics Advisory Committee of Singapore, Human Tissue Research[65] ("Singapore Report") states that:

> […] we do not think that it is appropriate to resort to hard-coding specific rules in legislative form for the regulation of research and commercial activity in the genetic and genomic sciences. Overly specific rules run the risk of rapid obsolescence, and of abuse by those minded to be seen to comply only with the letter but not the spirit of the law. In general, we recommend legislative intervention only in situations where it is clear that effective professional self-regulation and a fair balance of rights and interests between individuals and the public in encouraging research cannot be achieved without legislative teeth.[66]

The Report, however, does indicate that legislation must be enabling and that appropriate government agencies should exercise supervisory jurisdiction as gatekeepers.[67] It may be argued that despite some differences, the Ugandan and South African systems display many similarities to the UK and Australian frameworks, with regard to informed consent and the secondary uses of samples; however, in Uganda, there are specific differences in approaches to ownership and significantly more emphasis placed on community engagement and the responsibility of REC functioning. It is evident that these developing and developed world countries share the same areas of concern in respect of biobank research. All compared countries do not rely exclusively on legislative documents only, but also incorporate aspects of ethical principles into their scope of governance. Although certain aspects of governance require improvement, each country has developed basic guiding principles for ethico-legal regulation of biobank research, and in certain instances, the developing countries have taken bold steps toward putting forward principles which are markedly different to and challenge the traditional functioning of the developed world. However, although concepts differ to an extent in these developed and developing world countries, these differences identify the priorities and requirements of African frameworks in comparison to developed frameworks based on accepted Western ideologies.

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34. Nnamuchi O. Biobank and genomic research in Uganda: Are extant privacy and confidentiality regimes adequate? *Journal of Law Medicine and Ethics* 2016;44(1):85–95.
35. Whitworth JAG, Kokwaro G, Kinyanjui S, Snewin VA, Tanner M, Walport M, *et al.* Strengthening capacity for health research in Africa. *Lancet* 2008;372(9649):1590–3.
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37. See note 34, Nnamuchi O 2016, at 87: "HIV/AIDS prevalence in the country, although declining remains unacceptably high. Uganda leads the rest of East African countries in prevalence rate, and in 2013 accounted for 10 percent of all new infections in sub-Saharan Africa." See also: Chan BT, Weiser SD, Boum Y II, Siedner MJ et al. Persistent HIV-related stigma in rural Uganda during a period of increasing HIV incidence despite treatment expansion. *AIDS (London, England)* 2015;29(1):83–90.
38. The H3Africa, Human, Heredity & Health in Africa website, available at http://www.h3africa.org/ (last accessed 26 Jan 2017).
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41. The Constitution of the Republic of Uganda, 1995; available at http://www.usig.org/countryinfo/laws/Uganda/CONSTITUTION%20OF%20THE%20REPUBLIC%20OF%20UGANDA%201995.pdf (last accessed 26 Jan 2017).
42. The Public Health Act 1935; available at http://www.ulii.org/ug/legislation/consolidated-act/281 (last accessed 26 Jan 2017).
43. Uganda's National Council for Science and Technology, National Guidelines for Research Involving Humans as Research Participants, 2014 July; available at https://www.swarthmore.edu/sites/default/files/assets/documents/institutional-review-board/Human_Subjects_Protection_Guidelines_July_2014.pdf (last accessed 26 Jan 2017).
44. In accordance with Research Ethics policies: "The Ugandan National Council for Science and Technology (UNCST) has a mandate to facilitate and coordinate the development and implementation of policies and strategies for integrating Science and Technology (S&T) into the national development process. The UNCST is also tasked with overseeing the appropriate application of research ethics policies and practices within Uganda"; available at http://www.ccghr.ca/resources/harmonization/uganda/uganda-research-ethics/ (last accessed 26 Jan 2017).
45. See note 43, National Guidelines for Research Involving Humans as Research Participants 2014, at 1.
46. See note 34, Nnamuchi 2016, at 88.
47. See note 43, National Guidelines for Research Involving Humans as Research Participants 2014, at 2 which states that:

"Human Research Participants have a right to, inter alia:

a. Participate in research or not or withdraw at any time without penalty;
b. Be respected, including the right of their autonomy, culture, beliefs, and values;
c. Information about the research (it is important to ensure that information is communicated in understandable language, format, and in a conducive environment at all stages of the research);
d. Protection against research related injuries, harm, exploitation, and any other forms of abuse;
e. Privacy and confidentiality of their participation, during and after the research;
f. The standard of healthcare that is established nationally;

g. Treatment and management of research-related injuries; and
h. Reimbursement for costs associated with their participation in the research." at 2.

48. See note 43, National Guidelines for Research Involving Humans as Research Participants 2014, at 2.
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51. The Constitution of the Republic of South Africa. *South African Government*; available at http://www.gov.za/documents/constitution/constitution-republic-south-africa-1996-1 (last accessed 7 Nov 2017).
52. National Department of Health Ethics in Health Research: Principles, Processes and Structures. 2nd ed. 2015.
53. The International ethical guidelines for health-related research involving humans prepared by the Council for International Organizations of Medical Sciences in collaboration with the World Health Organization prepared by the Council for International Organizations of Medical Sciences in collaboration with the World Health Organization Geneva (CIOMS Guidelines) 2016; available at https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/ (last accessed 08 Nov 2017).
54. See note 53, CIOMS Guidelines 2016, at 43.
55. See note 52, National Department of Health Ethics in Health Research: Principles, Processes and Structures, at 30.
56. The NHS, Health Research Authority, Questions and Answers—The Human Tissue Act 2004. Code of Practice on the import and export of human bodies, body parts and Tissue; available at http://www.hra.nhs.uk/resources/research-legislation-and-governance/questions-and-answers-the-human-tissue-act-2004/ (last accessed 13 Dec 2017).
57. See note 26, Australian Government, NHMRC, National Statement on Ethical Conduct in Human Research 2007, at 40.
58. See note 43, National Guidelines for Research Involving Humans as Research Participants 2014, at 28–9.
59. De Vries, J, Munung SN, Matimba A, McCurdy S, Staunton O, Yakubu C *et al*. Regulation of genomic and biobanking research in Africa: A content analysis of ethics guidelines, policies and procedures from 22 African countries. *BMC Medical Ethics* 2017;18(8): 1–9.
60. *GN* R 182 in *Government Gazette* 35099 of 2 March 2012.
61. See note 26, Australian Government, NHMRC, National Statement on Ethical Conduct in Human Research 2007, at 44 which states that:

"Consent should be sought from appropriate community representatives as well as from the individuals concerned where:

(a) researchers propose to collect genetic material and information from individuals who are chosen because of their membership of a particular community;
(b) the research involves sensitivities for that community; and
(c) there is known to be a culturally relevant community structure involved in such matters."

62. See note 43, National Guidelines for Research Involving Humans as Research Participants 2014, at section 12.
63. See note 20, Chalmers D, 2015 at 703–13. See also, Knoppers BM, Saginur M. The Babel of genetic data terminology, *Nature Biotechnology* 2005;23:925–7, where the precision of the use of the term "reidentifiable" is questioned.
64. The International Ethical Guidelines for Health-related Research Involving Humans prepared by the Council for International Organizations of Medical Sciences in collaboration with the World Health Organization prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) Geneva 2016; available at https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/ (last accessed 08 Nov 2017); WMA Declaration of Taipei on Ethical considerations regarding Health Databases and Biobanks *adopted by the 53rd WMA General Ass*embly,

Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, 2016 Oct; available at https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/ (last accessed 08 Nov 2017).

65. WHO Human Genomics in Global Health, Bioethics Advisory Committee, 2002. Report: Human Tissue Research. Singapore (Singapore Report); available at http://www.who.int/genomics/elsi/regulatory_data/region/wpro/096/en/ (last accessed 29 Jan 2017).
66. See note 65, Singapore Report at 32.
67. See note 65, Singapore Report at 32.