Harmonisation of Biobank Regulations in Africa: Lessons to be learned from Europe

1. Introduction

Since the success of the human genome project, biobanks have become integral in understanding the complex interplay between genetics and the environment in the development of diseases.[1] The development of genomic biobank research has demonstrated that research is increasingly no longer confined to one site, but is now often a global, multi-site affair. Biological samples can not only be used and reused, but clinical information can continue to be added to the sample.[2] These samples are easily transferred across borders and more and more research is reliant on access to these biological samples.[3]

Yet the governance of this research is challenging. At a local level the biobank is likely to have its own rules and procedures in place. These must be followed as well as any guidelines issued by the research ethics committee (REC). Nationally, legislation, regulations and national ethical guidelines may have specific provisions on biobank research. Internationally, treaties, directives or agreements may have relevance, as well as the guidelines from professional bodies such as the International Society for Biological and Environmental Repositories (ISBER). However, due to the globalisation of the research, many biobanks are collaborating together as part of international consortia and sharing samples. These international consortia, as well as their funders, will also have their own individual rules in place. This poses particular problems for researchers attempting to access these samples as they must now navigate the governance frameworks in each jurisdiction that the individual biobanks reside. Added to this complexity is that these laws, guidelines, frameworks and policies are often in conflict, leading to confusion for researchers and challenging the development and efficacy of collaborations. Unsurprisingly, this has led to calls for harmonisation at a transnational level.[4]

Despite these challenges, there has been an emergence of large and small scale biobanks across the world and an increasing number of biobank networks. International consortia such as the Public Population Project in Genomics and Society (P^3G) and the International Society for Biological and Environmental Repositories (ISBER) seek to promote collaborations and set standards, whilst protecting national laws and policies. Yet these developments have largely been focused in the developed world and until recently the African continent was largely neglected. Recently there has been a growth in local and national biobanks in Africa and this has been spurred on by the Human Hereditary and Health in Africa (H3Africa) project.

Although these developments are welcomed, the governance of biobanks raise particular problems in Africa. There is considerable cultural diversity across the continent and biological samples often have special significance not seen in the West. The H3Africa project requires collaboration across borders, but the extent to which governance frameworks can be harmonised may be challenging. However, lessons may be learned from the European experience as Africa scales up its biobank

[1] A Nyika, 'Ethical and practical challenges surrounding genetic and genomic research in developing countries' Acta Tropica 2009, 112(Supplement 1):S21-S31, S22. A Kettis-Lindblad et al, 'Genetic research and the donation of tissue samples to bioabanks. What do potential sample donors in the Swedish general public think?' (2005) 16(4) European Journal of Public Health 433-440, 433.

[2] Z Master, E Nelson, B Murdoch, T Caulfield, 'Biobanks, consent and claims of consensus nature methods' (2009) 9(9) *Nature* 885-888.

[3] J Harris, *Report and Recommendations: Networking Meeting for EU-Funded Biobanking Projects* (November, 2008), 1.

[4] C Staunton, K Moodley, 'Challenges in biobank governance in sub Saharan Africa' (2013) *BMC Medical Ethics* 14:35.

research efforts and this will be the subject of this paper. It will first consider the challenges in biobank governance generally before discussing biobank research in Africa. It will also examine the emergence of biobank governance in Europe and lessons that may be learned for Africa. While a clear governance framework in Africa can enhance the research process by facilitating collaborations between researchers in Africa and around the world, this paper will question whether a unified harmonised framework is possible or even desirable for Africa.

2. Governing biobanks: the challenges

Biobanks are a valuable resource in medical research as they can store large quantities of biological materials that can be readily accessed by researchers across the world. To date, the governance of biobank research has tended to fall within the traditional governance structures of medical research. This involves a mix of national legislation and regulations as well as REC requirements. However this system is not particularly suitable for biobank research as it is a system that is designed for one research project in one institution and jurisdiction and approval is required by the REC in the institution that it takes place. [5] Approval is front loaded, taking place prior to the commencement of the research, and the focus is on getting the protocol through the REC and the informed consent process. [6]

With biobank research, the storage of the biological sample is potentially indefinite and it can be reused in multiple research projects. This potential to reuse the sample gives it considerable value but it questions our traditional informed consent process. It can be difficult to re-contact donors each time the sample is to be used, thus there have been calls for broad consent, backed by the WHO and OECD, whereby donors can consent to future but unspecified uses of the sample.[7] Although such an approach is consent, it is certainly not informed, thus tiered consent[8] and dynamic consent[9] have all been advocated as alternatives in an attempt to strike a balance between protecting human participants and allowing the research to flourish. If we are to adopt these new forms of consent, the focus must be taken away from the informed consent process as being at the start of the research only, in favour of some form of ongoing consent. Who oversees this process is unknown, but it demonstrates the need to look at other forms of governance and oversight for this research.

These are all issues that individual jurisdictions must address, but are further complicated by the transnationalisation of the research, particularly where the research is being done by international consortia. Biological samples can easily be moved across borders and open access policies are a condition of many funders.[10] The governance frameworks remain nationally based and not in favour of open science, but are being used to govern this transnational research that relies on open science

[5] J Kaye, From single biobanks to international networks: developing e-governance' (2011) 130 *Human Genetics* 377,380.

[6] L Goskin, J Hodge, 'Genetic privacy and the law: an end to genetics exceptionalism' (1999) *Jurimetrics* 21-58.

[7] World Health Organisation *Proposed international guidelines on ethical issues in medical genetics and genetic services.* http://whqlibdoc.who.int/hq/1998/WHO_HGN_GL_ETH_98.1.pdf (accessed 24 November 2014). Council for International Organizations of Medical Sciences *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002).

[8] Z Master, D Resnik 'Incorporating exclusion clauses in informed consent for biobanking' (2013) 22(2) *Camb Q Healthcare Ethics* 203-212, 204.

[9] J Kaye, E A Whitley, D Lund, M Morrison, H Teare, K Melham, 'Dynamic consent a patient interface for twenty-first century research networks' (2015) 23 *European Journal of Human Genetics* 141, 141.

[10] Open access policies that release data to promote science is also encouraged under many agreements such as the Bermuda Principles of 1996, the Fort Lauderdale Agreement of 2009 and 2009 Toronto agreement.

policies. This can be time consuming and costly as researchers spend time trying to ascertain the rules in each jurisdiction, and rules and policies are often in conflict. In response many organisations are developing their own guidelines to govern the research.

Rather than clarify matters, we are left with a multitude of laws, policies, guidelines, standard operating procedures, frameworks and agreements. There is no consensus on the legal and ethical framework for governance and the state has less of a role. [11] National rules and policies will continue to have an important function, but bottom-up approaches to governance from local biobanks and also from public opinion is of increasing importance.[12]

Biobank research is not alone in the search for new governance frameworks as it is an issue for many new and emerging technologies. There are increasing calls for "better" or "smarter" regulation as interest groups, institutions and individual actors involved in governance grows.[13] The state is having less of a role to play as the influence of international bodies and in particular funding agencies grow. We are seeing a rise of new forms of governance that are informal, flexible, decentralised and polycentric.[14]

It is certain that what we do need is a flexible governance structure that can meet the demands of biobank research. The research is developing at such a pace that over prescriptive provisions may quickly become out-dated. However, how should this be balanced with the need to have detail to ensure that the rules to be followed are clear, consistent, legitimate and transparent in Africa? Principles based regulation (PBR), that moves away from prescriptive rules to high level principles, has been mooted for innovative technology.[15] Amid concerns that Europe seeks to "regulate everything", van Veen has proposed such a model that is based on a good governance framework and key principles such as transparency, accountability, the non-profit basis of biobanks, intellectual property rights and confidentiality of personal data, amongst others.[16] Such a model may be suitable for biobank research as the key issues tend to focus on consent, feedback to participants, public interest, protection of process, access, ownership and intellectual property rights.[17] The Tiss.eu project has reported that the differences in procuring, storing and transferring human tissues diverge at a national and institutional level making harmonisation "extraordinarily difficult." However there are commonalities between these policies that "might pave the way for an intensified exchange and adoption of existing national approaches and models."[18] Common goals and principles are applied to a particular research project and it avoids the problem of laws

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[11] D Dickenson, 'Human tissue and global ethics' (2005) 1(1) *Genomics Society Policy* 41-53. AM Capron, A Mauron, BS Elger, A Boggio, A Ganguli-Mitra, 'Ethical norms and the international governance of genetic databases and biobanks: findings from an international study' (2009) 19 *Kennedy Institute Ethics Journal* 2009 101–124.

[12] H Gottweis, 'Governing genomics in the 21st century: between risk and uncertainty' (2005) 24 (2) *New Genomics and Society* 175.

[13] AM Farrell, S Devaney, T Hervery, T Murphy, "Regulatory 'desirables' for new health technologies' [2013] 21 *Med LR* 1, 3.

[14] Ibid, 4.

[15] S Devaney, 'Regulate to innovate: principle based regulation of stem cell research' (2011) 11 *Medical Law International* 53, 54.

[16] As quoted in A Wagstaff, 'International biobanking regulations: the promise and the pitfalls' (2011) *Cancer World* 24, 26-27.

[17] J Kaye, 'Do we need a uniform regulatory system for biobanks across Europe?' (2006) 14 *European Journal of Human Genetics* 245, 246.

[18] Final Report *Evaluation of Legislation and Related Guidelines on the Procurement, Storage and Transfer of Human Tissues and Cells in the European Union – an Evidence-Based Impact Analysis* http://cordis.europa.eu/publication/rcn/14540_de.html, 7.

becoming outdated. Other research consortia have established particular governance structures known as 'Pop-up' governance to address issues particular to that consortium.[19]

However both PBR and pop-up governance cannot exist in a vacuum. Pop-up governance can only exist when there is an external governance framework in place.[20] Equally Devaney acknowledges that the flexibility of PBR must be tempered with some descriptive rules to assist with interpretation and compliance.[21] What is probably necessary is a combination of both. Due to the multitude of actors involved in governance, that includes but is not led by the state, governance is polycentric.[22] It requires sufficient flexibility that researchers can do their work without fear of the rules becoming outdated and that rules can be adapted to local circumstances. Yet it also requires sufficient detail so that more guidelines and policies are not required to develop to fill the vacuum left in the governance system.[23]

How can all of this be achieved so that there is some level of harmonisation of governance in Africa to encourage and support collaboration, while also ensuring that there is not an over proliferation of rules and procedures to fill perceived governance gaps? Embedded in this is the challenge of cultural diversity. Before Africa rushes towards a harmonisation of its governance framework, we must first consider whether it is desirable or achievable.

2.1 Biobanking in Africa

Globally, biomedical research is disproportionately favoured towards those populations who can afford medical research. An estimated 10% of research funds is focused on diseases that affect 90% of the world's population to the benefit of those in developed countries.[24] Genomic research is no different with genomic wide association studies generally focusing on populations of European descent,[25] thus perpetuating this global health inequality.[26] Africa is the most genetically diverse continent and the Khoe-San people from southern Africa have the world's oldest genetic lineage.[27] Yet previously the only involvement of the African population in genomic research was in the form of "parachute research" whereby samples were collected from African populations and used in labs in other developed countries, often without the knowledge of the donor and also without the involvement of any local investigator or researcher.[28] In parachute research, the samples are used in

[19] J Kaye, D Muddyman, C Smee, K Kennedy, J Bell, UK10K, 'Pop-up governance: developing internal governance frameworks for consortia: the example of UK10K' (2015) 11 (10) *Life Sciences, Society and Policy*.
[20] Ibid
[21] S Devaney, 'Regulate to innovate: principle based regulation of stem cell research' (2011) 11 *Medical Law International* 53, 60.
[22] J Black, 'Constructing and contesting legitimacy and accountability in polycentric regulatory regimes' (2008) 2 *Regulation and Governance* 137, 137.
[23] J Kaye, S McGibbons, C Heeney, M Parker, A Smart, 'Conclusions' in J Kaye, S Gibbons, C Heeney, M Parker, A Smart *Governing Biobanks: Understanding the Interplay between law and practice* (Hart Publishing, 2012) 310.
[24] L Doyal 'Gender and the 10/90 gap in health research' (2004) Bulletin of the World Health Organisation 82(3) 162,162. D Resnik 'The Distribution of Biomedical Research Resources and International Justice' (2004) 4(1) *Developing World Bioethics* 42-57, 42.
[25] AC Need, DB Goldstein 'Next generation disparities in human genomics: concerns and remedies' (2009) 25(11) *Trends in Genetics* 489-494, 489.
[26] J de Vries, M Parker, 'Genomic sovereignty and the African promise: mining the African genome for the benefit of Africa' (2012) 38 *Journal of Medial Ethics* 474-478, 474.
[27] E Check Hayden, 'African genes tracked back' (2013) 500(7464) *Nature* 514, 514.
[28] S Langat, 'Reuse of samples: ethical issues encountered by two institutional ethics review committees in Kenya' (2005) 19 *Bioethics* 537-549. A Nyika 'Ethical and practical challenges surrounding genetic and genomic research in developing countries. *Acta Tropica* 2009, 112(Supplement 1):S21-S31, S22. A Wonkam, MA

labs in other developed countries, often without the knowledge of the donor and also without the involvement of any local investigator or researcher.[29] As the sample is removed from its country of origin, not only has the research very little local impact, but this prevents the development of local capacity, infrastructure and expertise.[30] Tellingly, in a survey of 50 publications on PubMed that used Cameroonian DNA samples, only 14 publications had a local author.[31]

Unsurprisingly, this has led to a widening gap in clinical and laboratory research capacity between sub-Saharan Africa and other developed nations.[32] Inequalities in health research can often lead to inequalities in health[33] and parachute research does little to resolve this. Rather it leaves the African population with little control over the fate of these samples and their future use, and there is little incentive for sample recipients to use these samples in a manner that safeguards the interests of donors. Donors have clear preferences on the use, reuse and exportation of their sample,[34] but if these are removed from the country of origin, their preferences may not be enforceable. There is thus a real need to refocus the debate to respecting the rights of the African population, from first obtaining the sample, to the building up of the research programme, through to the establishment of a clear regulatory framework that protects donor and researcher interests.

The International HapMap project[35] and the Malaria Genomic Epidemiology Network (MalariaGEN)[36] began to develop genomic biobank capacity in Africa. However the H3Africa project is the biggest attempt at establishing biobanks in Africa. As well as improving research in Africa,[37] the H3Africa project seeks to improve intra-Africa collaborations, build up the necessary infrastructure and capacity and establish African biobanks. It aims to keep the samples in Africa for use by African researchers, thus addressing some of the exportation and exploitation concerns.[38] The project is a great opportunity for the continent in terms of resources and capacity development, as well as research that is targeted at the population, but also presents considerable legal and ethical challenges in the governance of this research. Consent, confidentiality and commercialisation are all

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Kenfack, WFT Muna, et al. Ethics of human genetic studies in Sub-Saharan Africa: the case of Cameroon through a bibliometric analysis (2011) 11(3) Developing World Bioethics 120-127, 123.

[29] S Langat, 'Reuse of samples: ethical issues encountered by two institutional ethics review committees in Kenya' (2005) 19 *Bioethics* 537-549.

[30] T Mduluza, N Midzi, D Duruza, P Nedebele, 'Maintaining respect and fairness in the usage of stored shared specimens' (2013) (Suppl 1) *BMC Medical Ethics* 57. J de Vries, S Bull, O Doumbo, M Ibrahim, O Mercereau-Puijalon, D Kwiatkowski, M Parker, 'Ethical issues in human genomics research in developing countries' *BMC Medical Ethics* (2011) 12:5.

[31] A Wonkam, W Muna, R Ramesar, CN Rotimi, MJ Newport, 'Capacity-building in human genetics for developing countries: initiatives and perspectives in sub-Saharan Africa' (2010) 13 *Public Health Genomics* 492–494, 492.

[32] S Dalal, M D Holmes, R S Ramesar, 'Advancing public health genomics in Africa through prospective cohort studies' (2010) 64 *J Epidemiol Community Health* 585-586. 586.

[33] J Volmink, 'Addressing inequalities in research capacity in Africa' *BMJ* 2005;331:705–6, 705.

[34] K Moodley, N Sibanda, K February, T Rossouw, 'It's my blood: ethical complexities in the use, storage and export of biological samples: perspectives from South African research participants' (2014) 15(4) *BMC Medical Ethics*.

[35] http://hapmap.ncbi.nlm.nih.gov/.

[36] https://www.malariagen.net/home.

[37] C Dandara, F Huzair, A Borda-Rodriguez, S Chirikure, I Okpechi, L Warnich, C Masimirembwa, H3Africa and the African life sciences ecosystem: building sustainable innovation (2014) 18(12) *OMICS* 2014 733-9, 734.

[38] H3A Consortium, 'Enabling the genomic revolution in Africa' (2014) 344(6190) *Science* 2014 1346-8, 1347. J de Vries, A Abayomi, J Brandful, K Littler, E Madden, P Marshall, O Okem-Boyer, J Seeley, 'A perpetual source of DNA or something really different: issues in the creation of cell lines for African genomics research' (2014) 15(60) *BMC Medical Ethics*.

to be addressed, but added to this is the importance of the community in African society as well as the cultural significance of blood and other biological samples in many communities.[39]

Part of the H3Africa project is a mandate to address the ethical, legal and social issues that arise in the research and the Working Group on Social and Ethical Issues are seeking to introduce policies on many of the issues raised.[40] However, although the H3Africa project is bringing many of these issues to the fore, other biobanks independent of the H3Africa project are being set up across the continent.[41] These biobanks all have differing local, national and international rules and policies to follow. For example, in South Africa, oversight of research is done by the REC in each institution. Due to the particular issues involved and the scientific expertise necessary, the University of Witwatersrand has established its own Biobank Ethics Committee and separate policies on the establishment of a biobank.[42] At a national level, there is the National Health Act 2003 and accompanying regulations promulgated in 2012 that govern the use of tissues as well as the exportation of tissues. The Department of Health's ethical guidelines must also be followed.[43] The South African governance system permits broad and tiered consent as well as exportation of samples, subject to certain conditions. This is in contrast to other African countries that do not have specific pronouncements on consent or exportation, yet South African institutions may wish to collaborate with institutions from these other countries.

Governance frameworks differ across countries on the continent and it is in this environment that H3Africa is seeking to encourage and promote collaboration. Arguably for this to occur there will be a need for some harmonisation across jurisdictions. H3Africa can be a vehicle for harmonisation, but there is the danger that it will only add to the growing number of policies in this area. An overpopulation of conflicting biobank policies and regulations will do little to promote collaboration but will rather be a real challenge to governing biobank research in Africa. Good governance ensures clarity on the policies to be followed for the researcher; like issues should be similarly treated, thereby encouraging consistency and promoting the integrity of the biobanks.[44] Thus before the H3Africa project seeks to start a harmonisation drive, considerable of what is possible and achievable is necessary.

2.3 Biobank governance in Europe

[39] P Tindana, C Molyneux, M Parker, 'Ethical issues in the export, storage and resuse of human biological samples in biomedical research: perspectives of key stakeholders in Ghana and Kenya' (2014) 15(76) *BMC Medical Ethics*. J Fairhead, M Leach, M Small, 'Where techno-science meets poverty: medical research and the economy of blood in the Gambia, West Africa' *Social Science Medicine* 63(4) 1109-1120. R Usphur, J Lavery, P Tindana, 'Taking tissue seriously means taking communities seriously' (2007) 8: 11 *BMC Medical Ethicsi.* B Coetzee, A Kagee, M Tomlinson, L Warnich, O Ikediobi, 'Reactions, beliefs and concerns associated with providing hair specimens for medical research among a South Africa sample: a qualitative approach' (2012) 7(11) *Future Virology* 1135. D Banyubala, 'Posthumous Organ Retention and Use in Ghana: Regulating Individual, Familial and Societal Interests' (2014) *Health Care Analysis* DOI:10.1007/s10728-014-0277-4.

[40] http://h3africa.org/consortium/working-groups/24-working-group-external-pages/128-tor-ethics-wg-exp. Recently B3Africa was launched. Funded by Horizon2020 it seeks to develop a shared legal and ethics framework for the sharing of samples and data between Europe and Africa, amongst other issues. http://www.b3africa.org/

[41] A Dhai, 'Establishing national biobanks in South Africa: the urgenet need for an ethico-regulatory framework' (2013) 6 (2) *South African Journal of Bioethics and Law*.

[42] http://www.wits.ac.za/academic/researchsupport/23870/.

[43] South African Department of Health *Ethics in Health Research* 2nd ed (2015).

[44] J Kaye, From single biobanks to international networsk: developing e-governance' (2011) 130 *Human Genetics* 377, 379.

Biobanks in Europe are governed by international guidelines, Council of Europe recommendations, European Union (EU) regulations, national regulations, legislation and guidelines, REC guidelines, funding body requirements, guidelines established by the biobank itself and any consortia to which it belongs. This mix of local, national and transnational regulation can be problematic as they each have differing legal status and often overlap and contradict. The use, re-use and transfer of samples require a navigation of these regulations as well as the consent under which the sample was obtained. It can lead to difficulty in international collaborative research which relies on the transfer of biological samples across borders as well as confusion for those seeking access to the sample. It is thus unsurprising that the European Commission has claimed that harmonisation of biobank frameworks is necessary to ensure the cross border transfer of samples and research, as currently national policies are often in conflict negatively impact cross border initiatives and collaboration.[45]

First to consider are the international guidelines from the World Medical Association,[46] the World Health Organisation (WHO)[47], the OECD[48] and the UNESCO Declaration on the Human Genome and Human Rights.[49] They cover topics such as consent and confidentiality, but are non-binding and Europe is under no obligation to follow them. At a European level, the Council of Europe issued a recommendation on the exchange and transfer of biological samples in 1979[50] and human tissue banks in 1994.[51] Its most recent recommendation focused on research on human biological origins acknowledges that research is increasingly international and involving large quantities of biological samples.[52] The recommendation seeks to protect the rights of participants in biobank research and discusses consent, storage and anonymisation, amongst other issues.[53] As the first official European document on research on biological samples[54] it is significant, but there are some notable omissions from this recommendation including the ownership of samples, incidental findings as well as the use of biological samples from minors.[55] Furthermore it is a recommendation only, intended to provide guidance to Member States in drafting legislation rather than have any legal force itself.

Despite the non-enforceability of these international conventions, they do have a function. They can start a debate on biobank research and also provide a framework for individual biobanks and jurisdictions where none may exist. They also are part of PBR advocated by Devaney.[56] In the African context this is particular useful as it allows for cultural diversity. However they are quite general in nature, setting out principles rather than standards or procedures on the storage and use of samples

[45] European Commission *Biobanks for Europe: A Challenge for Governance* (2012), para 6.1.3.
[46] World Medical Association *The Declaration of Helsinki*.
[47] World Health Organisation *Proposed international guidelines on ethical issues in medical genetics and genetic services* (1998) [http://whqlibdoc.who.int/hq/1998/WHO_HGN_GL_ETH_98.1.pdf], World Health Organisation *Review of Ethical Issues in Medical Genetics* (2003).
[48] Organisation for Economic Cooperation and Development *Guidelines on Human Biobanks and Genetic Research Databases* (2006).
[49] UNESCO *Declaration on the Human Genome and Human Rights* (1998)
[50] Council of Europe *Recommendation No R(94) 1 of the Committee of Ministers to the Member States Concerning International Exchange and Transportation of Human Substances* 1979.
[51] Ibid.
[52] Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin.
[53] Ibid.
[54] Editorial, 'Research on human biological materials and the Council of Europe: some unanswered questions, overlaps and empty boxes' (2008) 15 *European Journal of Health Law* 1, 1.
[55] European Commission *Biobanks for Europe: A Challenge for Governance* (2012), para 6.1.1.
[56] S Devaney, 'Regulate to innovate: principles-based regulation of stem cell research' (2011) 11 *Medical Law International* 53.

and data.[57] They are also subject to interpretation, and differences in interpretation could potentially impede collaborations. Furthermore as illustrated, they are often non-binding leaving individual jurisdictions free to decide which, if any, sections to implement, and this is not a suitable approach for achieving a harmonised framework.

Unlike the OCED, the WHO and the Council of Europe, the treaties, directives and regulations of the EU have the force of law and must be followed by the Member States. Importantly, for some time the EU has been concerned with the promotion of good governance frameworks and in an effort to reduce bureaucracy and improve the regulatory process, it has sought to improve its legal proposals, reducing unnecessary or over-lapping rules and making its laws more understandable.[58] Known as 'Better Regulation' it is based on seven common principles: necessity, proportionality, subsidiarity, transparency, accountability, accessibility and simplicity.[59] Since 2010, the European Commission has also focused on smart regulation which is about "the whole policy cycle - from the design of a piece of legislation, to implementation, enforcement, evaluation and revision."[60] Part of this will be on ensuring that regulations are only introduced where necessary and in a manner that will improve the governance framework. Applying this to biobank research, new regulations should only be introduced if deemed necessary, based on an examination of the current policy and frameworks in place and the governance framework should follow the seven principles of Better Regulation.

A second important factor in this European governance is that the competences of the EU are to create an internal market and monetary union.[61] Research does not fall under these competences, but the European Commission has begun to take a much more active role in health since the Maastricht Treaty. This increased activity has not brought with it a coordinated response to regulating research and has very little impact on biobanking research. The Clinical Trials Directive has some influence as it requires an REC to review research and informed consent is necessary prior to the donation of a sample, but beyond this it has little impact. The safety and quality of tissues have also been addressed, but this applies to therapeutic use only and not research resulting in a lack of specific regulations for biobanks.[62] Thus despite the potential of the EU to introduce some harmonisation, none has been forthcoming.

One exception is in relation to data. Data, including data from an identifiable biological sample, is governed by the Data Protection Directive.[63] This directive was introduced in a response to the recognition that differing national legislation was potentially preventing the transfer of data across Member States, but it also seeks to protect the privacy of individuals. However protections in the directive pertain to data only and not the biological sample.[64] There thus seems to be a distinction in

[57] J Kaye, 'Do we need a uniform regulatory system for biobanks across Europe?' (2006) 14 *European Journal of Human Genetics* 245, 247.
[58] Commission, 'Better Regulation-Simply Explained' (2006) 3.
[59] Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, 'A Strategic Review of Better Regulation in the European Union' COM (2006) 690 final, COM (2006) 691 final. Mandelkern Report on Better Regulation (2001) i.
[60] Commission communication *Smart Regulation in the European Union* COM(2010)543 (8 October 2010).
[61] Article 3 (*ex* Art 2).
[62] Directive 2004/23/EC on setting standards of safety and quality for the donation, procurement, testing, preservation, storage and distribution of human tissues and cells. E Zika, T Schulte, J Kaye, A Brand, D Ibarreta, 'Sample and data use and protection in biobanking in Europe: legal issues' (2008) 9(6) *Pharmacogenomics* 773, 774.
[63] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data. See also Opinion 6/2000 on the Human Genome and Privacy, Working Document WP 91 on Genetic Data 5062/00/EN/FINAL WP 34.
[64] Opinion 4/2007 of Data Protection Working Paper.

law between data and the biological samples from which data is extracted[65] and different consent requirements can apply to the sample and data. It does seem rather peculiar that there was a need to regulate the data but not the sample itself, but for now, the protection of biological samples is not part of the European constitutional order. However, what the Data Protection Directive does demonstrate is that full harmonisation is not always possible, as its implementation differs across Member States. The directive requires that stored data be anonymised, but many jurisdictions consider that double coding is acceptable.[66] This can lead to challenges as if there is no one model for sharing data, comparisons between studies may be problematic.[67]

A final point to note is that the EU has no role in the regulation of ethics. The European Group on Ethics (EGE) was established to provide ethical guidance to the European Commission[68] and in 1998 it released an Opinion on human tissue banking that recommended European standards on safety and quality.[69] However, although regulations were subsequently introduced on this matter, it is an advisory body only and there is no obligation for the Commission or the Member States to follow its Opinions. Thus its Opinions has the same fate as many international guidelines: they may start debate and provide guidance, but unless adopted by the Commission, have no enforceability.

2.3.1 Biobank governance in Europe-has harmonisation hindered development?

It is therefore the responsibility of the Member States to govern biobank research and they differ in their approach: some have developed specific legislation, while others have provisions integrated into wider legislative provisions.[70] There are some common trends between countries: generally accreditation should be sought by a relevant competent authority, a registry of biobanks should be established with the coding of samples if they cannot be anonymised.[71] Certain national bodies such as the Human Tissues Authority in the UK have some national oversight. However that is generally limited to the issuing of licences for research and ensuring compliance with the law. Oversight of the use of sample is primarily conducted at a local REC level that are tasked with reviewing biobank protocols. Thus governance of biobanks can vary according to the individual jurisdiction and the individual biobank.

The lack of a harmonised governance framework in Europe has meant that the secondary use of samples in one country may be prohibited or restricted in another and may result in the unlawful use of samples where collaborations require the sharing of samples across borders.[72] There has been

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[65] E Zika, T Schulte, J Kaye, A Brand, D Ibarreta, 'Sample and data use and protection in biobanking in Europe: legal issues' (2008) 9(6) *Pharmacogenomics* 773,

[66] A Wagstaff, 'International biobanking regulations: the promise and the pitfalls' (2011) *Cancer World* 24-25. Double coding is when

"data and samples are initially labelled with a single specific code and do not carry any personal identifiers. The data and samples are then relabelled with a second code, which is linked to the first code via a second coding key. It is possible to trace the data or samples back to the individual by the use of both coding keys."

European Medicines Agency, *Definitions for genomic biomarkers, pharmacogenomics, pharmacogenetics, genomic data and sample coding categories* (EMEA/CHMP/ICH/437986/2006) November 2007.

[67] C Thomas Scott, T Caulfield, E Borgelt, J Illes, 'Personalised medicine-the new banking crisis' (2012) 30(2) *Nature Biotechnology* 141, 145.

[68] http://ec.europa.eu/bepa/european-group-ethics/welcome/index_en.htm.

[69] Opinion 11 European Group on Ethics *Ethical Aspects of Human Tissue Banking* July 1998.

[70] The United Kingdom enacted the Human Tissues Act 2008 and Estonia has passed the Biobanks Act 110/2000.

[71] European Commission *Biobanks for Europe: A Challenge for Governance* (2012), para 6.1.3.1.

[72] J Kaye, 'Do we need a uniform regulatory system for biobanks across Europe?' (2006) 14 *European Journal of Human Genetics* 245, 245.

considerable uncertainty in how best to address these challenges,[73] with many calling for a pan-European infrastructure for the ethical, legal and social issues (ELSI).[74] In recent years, EU funded projects have begun to consider these issues through a project on the implementation of the Data Protection Directive in medical research (PRIVIREAL), protection of fundamental rights and privacy in relation to genetic information and biobanks (PRIVILEGED), confidentiality and protection of data (Tiss.EU), amongst others.[75] Many organisations and institutions have also sought to develop best practices on the technical aspects of biobanks as well as for the ethical and legal issues, in the hope that this can promote a unified approach to biobank research.[76] However, these organisations must still operate within the differing legal frameworks of each state, a real challenge in the development of large scale collaborative projects, and can lead to duplication of effort and wastage of resources.[77]

Yet the recognition that harmonisation efforts could encourage the fluid interchange of samples and data across borders,[78] has seen efforts to reach this goal continue. Of significance is Article 179 and 187 of the TFEU on the establishment of a European Research Area and structures that may be necessary to develop research within the Union. Out of this, the European Research Infrastructure Consortium (ERIC) was established to provide the legal framework for the establishment of research infrastructures across Europe.[79] In 2006, the European Strategy Forum on Research Infrastructures (ESFI) recommended the establishment of the biobanking and biomolecular resources research infrastructure (BBMRI)[80] to

> "integrate the existing quality controlled biobanks, biomolecular resources and enabling technologies into a novel pan-European biomedical Research Infrastructure, and guided the way towards the establishment of high quality de novo European biobanks".[81]

The preparatory phase (PP) of the project lasted between 2008 and 2011 and €5 million was granted to fund the conceptualisation and securing of funding for the BBMRI.[82] It sought to collect biological samples that are linked to continually updated health information and to be a coordinating hub of activities, including collection, management, distribution and analysis of samples from European Member States.[83] This phase also involved a review and analysis of the ethical, legal and social issues that resulted in the coordination of the ethics review process, a policy on the protection of cross-border data and the development of tools to promote harmonisation. These included a WIKIE+ legal platform to disseminate documents currently used in EU countries and other web based tools on the legal requirements for the transfer of samples and transparency in transfer.[84] In November 2013, the BBMRI became an ERIC (BBMRI-ERIC) with its seat in Austria. Rather than devising a new set of

[73] C Thomas Scott, T Caulfield, E Borgelt, J Illes, 'Personalised medicine-the new banking crisis' (2012) 30(2) *Nature Biotechnology* 141, 147.
[74] J Harris, *Report and Recommendations: Networking Meeting for EU-Funded Biobanking Projects* (November, 2008), 16.
[75] *Ibid*.
[76] J Vaught, N Lockhart, 'The evolution of biobanking best practices' (2012) 413 (19-20) *Clin Chim Acta* 1569-1575.
[77] N Salminen-Mankonen, J E Litton, E Bongcam-Rudloff, K Zatlouka, E Vurio, 'The pan-European infrastructure for biobanking and biomelcular resouces: managing resources for the future of biomedical research' (2009) 15(2) *embnew.news.*
[78] European Commission *Biobanks for Europe: A Challenge for Governance* (2012), para 4.1.
[79] http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=eric1.
[80] *European Strategy Forum on Research Infrastructures Roadmap on Research Infrastructures Report 2008,*48
[81] *Biobanking and Biomolecular Resources Research Infrastructure* Final Report 2011, 3.
[82] *Ibid*.
[83] European Strategy Forum on Research Infrastructures *Roadmap on Research Infrastructures Report*
[84] *Biobanking and Biomolecular Resources Research Infrastructure* Final Report 2011, 5.

regulations or guidelines for its members, it was decided that the laws of the country in which the research is conducted will govern it.[85]

BBRMI-ERIC has thus sought to find a solution that is workable in light of the current European governance framework. Its solution does not eradicate the challenges of the applicability of different laws and policies, but it is a platform that can help researchers navigate the myriad of laws, regulations and policies. Furthermore it may possibly influence EU policy by promoting the interests of the ERIC[86] and be a key player in a drive for a harmonised framework in Europe.

3. Governing biobanks in Africa: lessons to be learned

One of the greatest challenges to a harmonised biobank governance framework, both in Africa and around the world, is that the research is being conducted at a supranational level, but governance is still at a national level.[87] To resolve this problem in Europe, Kaye has recommended the development of a uniform regulatory structure and the establishment of a new independent European entity or body currently in existence that has enforcement powers and the ability to develop standards for biobanks.[88] The advantage of such a body is that the principles and standards would apply irrespective of the establishment of any new biobank.[89] This system remains elusive for Europe, but has not stopped the research from developing. Moving forward, Africa may consider that harmonisation has not been achieved in Europe, but note that there are a number of key points that should be considered as biobank research develops on the continent.

3.1 Importance of good governance

Biobank research in Africa is governed by a combination of local and national laws, regulations and guidelines. Similar to Europe, in some jurisdictions biobank research falls under general provisions on the use of tissue, while in others there are genomic biobank research specific policies. Coupled with this, there is the Declaration of Helsinki and other international agreements that must be considered and more recently, the H3Africa policies on informed consent, community engagement as well as the other policies that the group is currently developing.

A harmonisation of policies could assist in the development of collaborations to be formed under the H3Africa project. Incorporating differing national consenting requirements into one collaborative project, can lead to complicated consent forms for multi-national projects. A study by McGibbons *et al* revealed that potential collaborators from jurisdictions that had overly strict consenting requirements were excluded.[90] Unclear or inconsistent policies has forced some into taking more governance related steps than were probably necessary to make sure that they were compliant,[91] while others creatively interpreted the rules or selected those to be followed.[92] This proliferation of differing rules and procedures in Europe were in part due to the uncertainty in biobank governance

[85] J Reichel, AS Lind, M Hansson, JE Litton, 'ERIC: a new governance tool for biobanking' (2014) 22 *European Journal of Human Genetics* 1055, 1056.
[86] Ibid.
[87] J Kaye, From single biobanks to international networsl: developing e-governance' (2011) 130 *Human Genetics* 377, 380.
[88] J Kaye, 'Do we need a uniform regulatory system for biobanks across Europe?' (2006) 14 *European Journal of Human Genetics* 245, 248.
[89] Ibid.
[90] S McGibbons, A Smart, 'Attitudes to particular laws and governing bodies' in J Kaye, S Gibbons, C Heeney, M Parker, A Smart *Governing Biobanks: Understanding the Interplay between law and practice*, 188-192.
[91] Ibid, 187.
[92] S McGibbons, A Smart, 'General attitudes to governance' in J Kaye, S Gibbons, C Heeney, M Parker, A Smart *Governing Biobanks: Understanding the Interplay between law and practice* (Hart Publishing, 2012) 159.

in Europe, where at times researchers were forced to rely on their past professional experience as a basis in which to develop governance frameworks for the research.[93]

An over population of contradictory regulations and policies has meant that researchers often have to decide which to follow in Europe. The current system in Europe and the emerging trend in Africa is that biobanks are governed through a combination of national regulations and guidelines, with oversight generally in the hands of a local REC, leading to a confusing and bewildering governance space. Having multiple and sometimes contradictory ethics review can undermine transparency and accountability in any governance system.[94] This system should not be made any more confusing by creating a new set of rules or principles. Rather, attention should be given to the features of a good governance framework for Africa. Crucially the system must be flexible and adaptable to meet the developing science. Overly prescriptive legislation can quickly become outdated and may not be suitable for innovative research on the continent. The UK Biobank has developed an Ethics and Governance Framework (EGF) that is continuously revised and it's Ethics and Governance Council (EGC) develops policies and procedures as well as monitoring and overseeing the UK Biobank. Both the EGF and the EGC are continuously revised and updated and the EGC continuously has an open dialogue with the UK Biobank.[95] Laurie has argued that this type of "reflexive governance" whereby policies change over time in response to stakeholder deliberations and changing needs is much more suited to governing biobanks than hard law as it remains fit for purpose.[96] This continuing involvement of stakeholders is particularly important for African populations due to the importance of the community in African society.[97] There is a need for ongoing consultation with the community and its leaders throughout the project to seek their views on issues such as consent, commercialisation of research and feedback of results. The importance of community engagement for biobank research, particularly in Africa, must be recognised and a reflective governance framework that provides for this is to be welcomed.

With this in mind, a PBR approach that has certain key principles underpinning its governance framework may be most suitable. Laurie considers that the role of the law may thus be best confined to the protection of core principles or interests that should underpin biobank research.[98] The H3Africa High Level Principles on ethics governance and resource sharing are key values that underpin the Consortium, with discretion on how these principles are implemented. [99] Such an approach does bring with it flexibility, but is problematic for two reasons. First, regulations on biobank research across the continent are developed in isolation, with little or no regard for how their regulations will impact other jurisdictions. These principles are potentially subject to

[93] J Kaye, S Gibbons, C Heeney, M Parker, A Smart 'From an idea to a project' in J Kaye, S Gibbons, C Heeney, M Parker, A Smart *Governing Biobanks: Understanding the Interplay between law and practice* (Hart Publishing, 2012) 4.

[94] R Isasi, B Knoppers, 'From banking to international governance: fostering innovation in stem cell research' (2011) *Stem Cell International*.

[95] *See* UK Biobank *Ethics and Governance Framework* 2007 and UK Biobank Ethics and Governance Council http://egcukbiobank.org.uk/.

[96] G Laurie, 'Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law' (2011) 130 *Human Genetics*, 347.

[97] G Ramjee, N Coumi, N Dladla-Qwabe, S Ganesh, S Gappoo, R Govinden, V Guddera, R Maharaj, J Moodley, N Morar, S Naidoo, T Palanee 'Experiences in conducting multiple community-based HIV prevention trials among women in KwaZulu-Natal' (2010) 7 (10) South Africa AIDS Research and Therapy.

[98] G Laurie, 'Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law' (2011) 130 *Human Genetics*, 347, 351.

[99] H3Africa *High Level Principles on Ethics, Governance and Resource Sharing* (2013) available at http://h3africa.org/about/ethics-and-governance.

considerable differences in interpretation and this will do little to improve harmonisation across the continent. Second, only those projects funded by H3Africa are subject to the principles and they are not enforceable across the entire continent. A pan-African response to biobank research would be preferable as it would speak for the continent rather than those in receipt of H3Africa funds. H3Africa does not have the authority to speak for the entire continent, and we may see the emergence of other guidelines and policies spring up for biobank research in Africa that may claim to speak for particular groups across the continent.

However due to its position, H3Africa can play a leading role in this, in much the same way as BBMRI is playing in Europe. The ethos of smart regulation whereby only necessary regulations are to be introduced should be endorsed by the Consortium. Its focus should equally be on the promotion of good governance as well as the substance of the policies in place. In their study on the governance on the use of biological data and samples in England and Wales, McGibbons *et al* found that the system did not follow the principles of good governance. It lacked consistency due to the lack of coordination and single body for decisions making, the system lacked transparency as it reportedly difficult to know what rules applied and who was to enforce the rule and due to the considerable financial and resource costs involved, the system was not proportionate.[100]

Currently, biobank research in Africa can be subject to similar criticisms. There is no one body responsible for coordination of activities either nationally or for the continent, and it is often difficult to know what rules to follow. For example, if funding conditions require open access policies that may be contrary to the rules in one jurisdiction, what are the implications for the researcher and can they be removed from the Consortium? H3Africa should take a lead in outlining the features of a good governance framework for biobank research in Africa. The "Better Regulation" Principles adopted by the European may be a good starting point, but these should be adopted for biobank research on the African continent.

3.2 Move towards harmonisation

It is submitted that there should be no rush to legislate or introduce new polices for biobank research in Africa. First there must be an understanding of the governance framework in place and a consideration of the features of good governance for biobank research. However, there have been calls for harmonisation and it has been demonstrated that differing policies can impede collaborations in Europe. Despite the adaptability and flexibility of a PBR framework, there is the need for some form of legislation and enforcement powers. The abuses exposed in the Havasupai tribe case whereby samples were collected for a study on diabetes but used in studies on schizophrenia, inbreeding and evolutionary genetics that challenged the Tribes own account of its origins, demonstrate that researchers will not always have the best interests of the donors at heart.[101]

However, how can these differing national frameworks be accommodated considering the internationalisation of the research? Despite calls for harmonisation, the cultural diversity in Africa as well as the differing governance approaches, leads one to conclude that harmonisation is unlikely to be successful. Attempts at harmonising strict with liberal policies often results in the creation of a

[100] J Kaye, S McGibbons, C Heeney, M Parker, A Smart, 'Conclusions' in J Kaye, S Gibbons, C Heeney, M Parker, A Smart *Governing Biobanks: Understanding the Interplay between law and practice* (Hart Publishing, 2012) 310-317.

[101] M Mello, L Wolf, 'The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples' (2010) 363 *New England Journal of Medicine* 204-207.

framework that is comprised of the rules of the strictest regime.[102] In Europe, projects that sought to "aim for the highest legal standard in a project" with the aim of meeting the legal requirements in each jurisdiction, found that they had to leave collaborators with onerous national requirements out of the project as they could not meet these strict national requirements.[103]

How can Africa deal with these conflicting regulations so as not to impede upon collaborations? The "minimal threshold of policy harmonization" is favoured by some cross country biobank projects.[104] Another solution is the coordinating principle whereby tissue samples are handled in accordance with the rules of the country that they were obtained from.[105] This rule was adopted by Tubafrost who opted not to introduce their own polices in light of the differing policies and regulations across Europe as they believed that national policies diverged to such an extent that consensus would have been impossible.[106] There was the concern that if an attempt at consensus was made, it would have resulted in the strictest regime being implemented, to the detriment of those countries where a more liberal regime was in place.[107] Thus Tubafrost opted for a coordinating principle based on the home country rule whereby the rules of the home country dictates whether the sample can be used abroad:

> "if tissue may legitimately used for a certain kind of research in the country where it was taken and under whose jurisdiction the patient falls, it may also be used for such research in the country where it is sent to in the context of a scientific program even if in that other country other regulations would apply for research with residual tissue taken from patients under their jurisdiction'.[108]

Until such time as a pan-African response to biobank research is possible, or the coordinating principle is adopted, H3Africa should be cognisant of the experiences of Europe and perhaps follow the example of Tubafrost in declining to introduce new policies that confuse matters. Rather its energy should be spent on the development of a WIKIE+ legal platform similar to that of BBMRI-ERIC that describes the legal situation in each country. Such a development could help African researchers navigate the governance framework that exists in each country.

3.3 Biological data

The unique features of biobank research causes us to reassess previously held ideals about the ethical conduct of research. However the greatest risk in this research is confidentiality. As DNA is an identifier, confidentiality can no longer be guaranteed.[109] Furthermore, considerable data comes

[102] A Wagstaff, 'International biobanking regulations: the promise and the pitfalls' (2011) *Cancer World* 23, 26.
[103] J Kaye 'Reflections on practice and governance ' in J Kaye, S Gibbons, C Heeney, M Parker, A Smart *Governing Biobanks: Understanding the Interplay between law and practice* (Hart Publishing, 2012) 279.
[104] KJ Maschke, 'Navigating an ethical patchwork-human gene banks' (2005) 33 *Nat Biotechnol* 539-45.
[105] A Wagstaff, 'International biobanking regulations: the promise and the pitfalls' (2011) *Cancer World* 23.
[106] TubaFrost was set up in 2003, initially funded by the European Commission under FP5 and later by the Organisation of European Cancer Institutes: "The consortium was able to set up the European virtual frozen tumor tissue bank. From which the standardization, the code of conduct for exchanging samples in Europe and the rules for access and use with incentives for the collectors are widely used in different projects throughout Europe." For more information *see* http://www.tubafrost.org/research/indexproject.php.
[107] E van Veen, P Riegman, W Dinjens, K Lam, M Oomen, A Spatz, R Mager, C Ratcliffe, K Knox, D Kerr, B van Damme, M van de Vijver, H van Boven, M Morente, S Alonso, D Kerjaschki,I Teodorovic, M Isabelle, A Passioukov, S Lejeune, P Therasse, J Oosterhuis, 'TuBaFrost 3: Regulatory and ethical issues on the exchange of residual tissue for research across Europe' (2006) 42 *European Journal of Cancer* 2914-2923, 2519.
[108] Ibid, 2914.
[109] H Widdows, S Cordell, 'The Ethics of Biobanking: Key Issues and Controversies Heather *Health Care Anal* (2011) 19:207–219. B Malin, L Sweeney, 'How (not) to protect genomic data privacy in a distributed network:

from these samples and it is unclear how this data should be treated and protected. Biobank governance in Africa is generally accommodated within the existing protection of human participants in research that often does not have much consideration of biological data. In September 2015, the South African insurance company Discovery announced that on foot of a deal with a US company, they would offer genetic testing for $250. Of concern is that their de-identified data would be stored in the US.[110] South Africa has currently no legislation in place to deal with these issues and it is not alone as it has not been subject to the same oversight as biological samples. However the value and need to protect this data must not be underestimated as it is the linkage of data with samples that gives the sample scientific value.[111] In Europe, the biological sample and data from the sample are treated as being legally distinct. This distinction is challenged on the grounds that genetic material "is *both* information *and* bodily sample" creating uncertainty at times as to what should be considered data or a sample.[112]

Material transfer agreements (MTAs) and data sharing agreements can make up for policy gaps and establish agreements on which data is shared. However the original consent may not contain any reference to data. Should restrictions on the use and transfer of samples apply to data? Since this is an area that many African jurisdictions have not considered,[113] the control on the use of biological data is one area in which there could be a pan African response. The European experience has demonstrated that full harmonisation in this area is unlikely, but the conversation must be started on the protection of data and whether it should be on par with that of samples. Treating samples and data as being legally distinct may be a difficult concept for many researchers to grasp considering their interconnectedness, but an African response is necessary. As one of the greatest risks in biobank research, confidentiality of participants must be protected and this must extend to their biological data.

4. Conclusions

Genomic biobank research in Africa is entering an exciting and promising phase. Biobanks are increasingly interconnected networks and harmonisation of governance across the continent can assist in the development of collaborations. However biobanks have been developed over time and there has been an ad hoc and often local response to their governance. These frameworks must now oversee research that is increasingly conducted at an international level. UNESCO's *International Declaration on Human Genetic Data* calls for states to regulate the international transfer of data and samples to foster international collaborations. This is certainly an aspiration of many, but has not been possible within Europe due to the multitude of bodies that have the power to develop guidelines, policies, legalisation and directives making it difficult to agree on one set of rules or principles.

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using trail re-identification to evaluate and design anonymity protection systems' (2004) *Journal of Biomedical Informatics* 37(3):179-192.

[110] Cassidy S 'Discovery to offer genetic testing' http://www.iol.co.za/lifestyle/discovery-to-offer-genetic-testing-1.1920337#.VhJuuCvd2y5.

[111] G Gaskell, H Gottweis, J Starkbaum, M Gerber, J Broerse, U Gottweis, A Hobbs, I Helen, M Paschou, K Snell, A Soulier, 'Public and biobanks: Pan-European diversity and the challenge of responsible innovation' (2013) 21 *European Journal of Human Genetics* 14, 14.

[112] J Kaye, S Gibbons, C Heeney, M Parker, A Smart 'From an idea to a project' in J Kaye, S Gibbons, C Heeney, M Parker, A Smart *Governing Biobanks: Understanding the Interplay between law and practice* (Hart Publishing, 2012) 5.

[113] South Africa has introduced the Protection of Personal Information Act 2013 but it remains to be seen the impact, if any, that this will have on biological data.

In response to new technologies, there is often the perceived need that the government ought to do something, often in the form of regulation.[114] However there should be some coordinated international response and as a consortium with expertise in science, law and ethics, H3Africa is ideally situated to start this conversation. H3Africa can lead this discussion. It should not use its pivotal position to develop new and possibly unnecessary guidelines, but rather lead a discussion on the principles of good governance and the role it can play in achieving harmonisation. The conversation should begin by focusing on the importance of establishing good governance principles that should underpin a biobank framework. The system should be transparent, proportionate, and consistent, while allowing for flexibility and legitimate and it should create an environment that fosters collaboration, while ensuring public trust. Thus, moving forward, Africa must start a discussion on the governance of biobanks and how it can be structured in such a way that promotes collaborative research across the continent.

[114] AM Farrell, S Devaney, T Hervery, T Murphy, "Regulatory 'desirables' for new health technologies' [2013] 21 *Med LR* 1, 3.