Developing a Principles-Based Framework to Link the Governance of Genomics Research and Biobanking in Africa to Global Health Justice

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"It takes a village to raise a child" (African Proverb).

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Abstract

Background

Genomics research has introduced significant transformations in the way health research is traditionally structured. Firstly, genomics research often requires long-term storage of biological samples for future unspecified uses. Secondly, the stored samples may be shared with researchers across the globe for the purposes of research. Thirdly, genomics researchers are increasingly required to make their research data publicly available for use by other researchers and institutions from around the world. Whilst data and sample sharing offers significant benefits for global health research, in Africa, it is taking place amidst a background of: structural inequities in health and health research between Africa and High Income Countries (HICs). There are also concerns around the exploitation of African researchers and study populations, mainly hinged on historical experiences in global health research, what has been termed scientific imperialism or "extractive" research. It is therefore not surprising that the rise in genomics research and biobanking studies in Africa has been accompanied by strong calls to address the ethical legal and social issues (ELSIs) raised by genomics research and biobanking in Africa. Some of these ELSIs focus on individual-level issues (micro-justice), others go beyond that to include broader societal ELSIs (macro-level justice) such as: secondary access to samples and data, benefit sharing, exploitation of African researchers and populations, intellectual property and the ownership of samples and data. One way of addressing these macro-level justice-related ELSIs is through governance.

Aim and Objectives

The aim of this study is to develop a governance framework that could be used to address macro-level-justice-ELSIs in genomics research and biobanking in Africa.

To achieve this aim, I put forth the following specific objectives:

1. To identify principles, values and norms that could promote justice and fairness in genomics research and biobanking in Africa;

2. To develop a principles-based governance framework for genomics research and biobanking in Africa that links its policies to the promotion of justice;

3. To investigate how the governance of current day genomics research and biobanking projects in Africa have considered concerns of justice and fairness;

4. To explore the views of key stakeholders on fair and just governance mechanisms for genomics research and biobanking in Africa.

Methodology

To develop the governance framework, I used the normative practice-oriented bioethics (NPOB) approach. This required adopting a number of methodologies, both conceptual and empirical. The conceptual work used the convergence approach and consisted of a theoretical analysis of two theories of global health justice, namely: shared health governance (by Jennifer Ruger) and global governance for health (by Larry Gostin); as well as the African philosophy of *Ubuntu*. Through the conceptual and normative analysis, I identified a number of principles that could inform the governance of genomics research and biobanking in Africa. These principles were used to propose a governance framework that could address macro-level justice ELSIs in genomics research and biobanking programs in Africa.

Following the development of the governance framework, we used empirical bioethics research methods to probe whether and how the framework's principles could be practically promoted in genomics research and biobanking consortia in Africa and to revise the framework where necessary. To do this, I used the reflective equilibrium approach. This included checking the proposed framework's principles and recommendations against current governance practices of a genomics research consortia in Africa as well as well as prompting various stakeholders to think of how these principles could be applied in practice, or how the have been applied within genomics research consortia in Africa. Using the Human Heredity and Health in Africa (H3Africa) Consortium as a case study, as well as two qualitative research methods: content analysis of H3Africa governance documents and one-on-one in-depth interviews (n=15), I checked the framework's principles against the empirical data and revised as, and when necessary (reflective equilibrium).

Results

The conceptual analysis led to the identification of the following nine principles: solidarity, reciprocity, furthering the ideals of health justice (FIHJ), shared sovereignty, shared resources, transparency, shared responsibility; mutual trust and mutual collective accountability. These principles were used to develop a principles-based governance framework for genomics research and biobanking. Because I wanted develop a governance framework that is practically implementable, I made recommendations on how each principle could be actualised genomics research in Africa.

Analysis of the empirical data showed that the majority of the framework's principles and or recommendations were being promoted or prioritized by H3Africa ELSI governance. Equally, many H3Africa the principles and recommendations were considered by various H3Africa stakeholders to be critical in promoting justice and fairness in genomics research and biobanking projects in Africa. This suggests that our framework's requirements are not just theoretical but could be implemented in practice and that there was some buy-in by stakeholders involved in genomics projects in Africa.

A key area of deviation between the principles-based framework and the empirical data was the involvement of study populations in decision making (e.g. decision making on sample and data use; research priority setting etc.) The empirical data however showed that there was little involvement of study populations in decision-making within the H3Africa consortium, our case study. Whilst the different stakeholders acknowledged the importance of including study populations in governance processes, there were parallel concerns about its practicability. Despite these, the conceptual analysis and interview data confirms that there is need to first and foremost consider study populations as a key stakeholder group that should be involved in decision making, including decisions on secondary use of samples and data and in the development of biobank policies that will directly affect them.

A new principle emerged from the empirical data. This was the principle of mutual respect. Following the reflective equilibrium approach, the framework was revised to include mutual respect as a core guiding principle.

Conclusion

Using the normative practice oriented bioethics approach, I have developed a novel, principles-based governance framework for genomics research and biobanking in Africa. This framework, which was derived following a conceptual analysis of the governance theories, as well as the reflective equilibrium approach, seeks to address justice-related-(macro-level)- ELSIs in genomics research and biobanking in Africa. It and is grounded in theories of global health justice and the African moral theory of *Ubuntu.* Although the framework was developed to support the governance of genomics research and biobanking in Africa, its principles are likely to be applicable to other forms of global health research.

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List of Abbreviations

AESA: Alliance for the Acceleration of Excellence in Science in Africa

AfSHG: African society of human genetics

APCDR: African Partnership for Chronic Disease Research

AGVP: African Genome Variation Project

B3Africa: Bridging Biobanking and Biomedical Research in Africa

DAA: Data Access Agreement

DALY: Disability Adjusted Life Years

DARP: Data Access Release Policy

DBAC: Data and biospecimen access committee

EGA: European Genome Archive

ELSI: Ethical, Legal and Social Issues

FIHJ: Furthering the Ideals of Health Justice

GGH: Global governance for health

GWAS: Genome Wide Association Studies

H3Africa: Human Heredity and Health in Africa

HGP: Human Genome Project

HIC: High Income Country

IEC: Independent Expert Committee

LMIC: Low and Middle Income Country

MalariaGen: Malaria Genomic Epidemiology Network

MCA: Mutual Collective Accountability

NIH: National Institute of Health

R4HJ: Research for Health Justice

REC: Research Ethics Committee

RFA: Research Funding Announcement

SHG: Shared Health Governance

WG: Working Group

WHO: World Health Organisation

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Chapter 1: Introduction, Study Overview and Objectives

There is an upsurge in the number of genomics research and biobanking projects in Africa. This is motivated, in part, by concerns that the near absence of genomics studies on African populations could cause a genomics divide between Africa and other parts of the world, and that this could in turn widen global health inequities (Singer and Daar, 2001b, H3Africa Consortium, 2014, Newport and Rotimi, 2009, WHO, 2002). Another reason that has been advanced for the importance of population genomics studies in Africa, is that Africa's rich genetic diversity is an essential resource for investigating the role of genomic variation in human health and disease (Gomez et al., 2014, Campbell and Tishkoff, 2008, Ramsay, 2012). Genomics research on African populations therefore offers potential not only in addressing global health inequities, but for improving human health globally (Rotimi et al., 2017). For the above reasons, a number of genomics research and biobanking consortia have been set up in a number of African countries. The majority of these projects, arguably, are funded by institutions in high income countries (HICs), involves collaborations between HICs and African researchers, and are sometimes organised in the form of a research consortium or network. Examples include: : the Southern African Human Genome Project (Pepper, 2011); The Malaria Genomic Epidemiology Network (The Malaria Genomic Epidemiology Network, 2008); the African Genome Variation Project (Gurdasani et al., 2015); the Human Heredity and Health in Africa (H3Africa) consortium (H3Africa Consortium, 2014) and the Bridging biobanking and Biomedical research (B3Africa) consortium.

Genomic research consortia in Africa, such as those listed above, are likely to encompass a number research projects, taking place across different countries both in and out of Africa. The advantage of this kind of research structure is that it facilitates the attainment of large samples sizes and datasets that are often required to get statistically significant results in population genomics studies. It is therefore common practice for genomics research consortia to set up as biobanks as a critical arm of the consortium. It is expected that the samples stored in the biobanks alongside the genetic data generated from the projects, will eventually be made available (publicly or otherwise) for to researchers and entities from around the world. This includes researchers who may not have been part of the primary studies that collected the samples or generated the data. In cases where the data is not openly available, researchers, policy makers and innovators or other interested parties may apply to an identified body (research ethics committee, data access committee etc.) for permission to access and use the data. Genomics has therefore introduced significant transformation in the way health research is typically structured, whereby a single research group focused on a specific project and samples and data were used for that specific project and not stored for future unspecified uses.

Considering that the majority of genomics research and biobanking consortia in Africa are funded by agencies in HICs, and involve researchers from both HICs and African countries, they could be categorized as international health research. Also, because a good number of these studies aim to address health issues of pertinence to African populations, and possibly prevent a genomics divide between HICs and LMICs that could widen global health inequities, they could be considered as global health research[1]. Global health research has often played a significant role in: advancing health research in Africa, supporting research in HICs; and in reducing global health inequities (Dye et al., 2013b, GFHR, 2004, GFHR, 2008, Dye et al., 2013a, Benatar, 2001). Despite these benefits, global health research in Africa has sometimes been linked to the exploitation of African researchers and study populations (Benatar, 2000, Bhutta, 2002, Hawkins and Emanuel, 2008).

The sharing of samples and data in global has been a major cause of contention in global health research programs in Africa-It raises ELSIs that border on scientific imperialism and the exploitation of African researchers and study populations (Barchi et al., 2015, Nienaber, 2011, Tindana et al., 2014, Upshur et al., 2007, Tangwa, 2017). The underlying causes of exploitation of African researchers and study populations in global health research are related to disparities in biotechnology and research resources between Africa and HIC partners; and as the high disease burden in Africa. These disparities tend to confer more benefit for HIC research partners and may lead to perceptions of exploitation and imperialism in global health research (Benatar, 1998, Crane, 2013). For example differences in research resources between HICs and African countries could see the HIC partner setting the research agenda and defining research processes and resource allocation in ways that could be considered paternalistic by the African collaborators. Al these are concerns of inequities that would require a justice lens (Pratt and Loff, 2011, Pratt and Loff, 2014, Benatar, 2001, de Vries et al., 2015b, Molyneux and Geissler, 2008).

Discussions on justice and fairness in genomics research and biobanking in Africa has been dominated by discussions around the possible exploitation of African researchers and study populations (de Vries and Pepper, 2012, de Vries et al., 2015c, Munung et al., 2017). This is because the export of samples and the sharing of data is an integral part of contemporary population genomics studies in Africa. Yet, sample export has been at the center of controversies around international health research conducted in Africa. The concept of “parachute” or “fly in, fly out” research in LMICs (Okwaro and Geissler, 2015, Smith, 2018, Heymann et al., 2016) has no doubt left a strain on global health research collaborations that plan to export samples and

[1]For differences between global health research and international health research, see Ooms G (2014. From international health to global health: how to foster a better dialogue between empirical and normative disciplines. BMC International Health and Human Rights: 14(1):36.

data. Genomics research in Africa or other form of global health research in Africa that plans to export samples and/or share research data will have to invest a lot of efforts in addressing concerns of "parachute" or "extractive" international health research in Africa. This will require these genomics research consortia, to first and foremost unpack the justice-related ethical issues that underlie concerns of exploitation; then identify ways by which they could be addressed. This is important not just for successful implementation of genomics studies in Africa, but also for the long-term sustainability of these projects and subsequent ones. Also, whilst one of the motivating factors for the huge investments in population genomics studies in Africa is the fear that the absence of genomics studies on African populations may widen global health inequities. A pressing question therefore is, how can genomics research and biobanking consortia in Africa ensure that their activities address concerns of global health inequities. This thesis seeks to suggest ways in which justice-related ethical issues in genomics research and biobanking consortia in Africa could be addressed.

1.1 Study Aim and Objectives

Power and economic disparities between LMICs and HICs, and global health inequities are the main forces behind concerns of exploitation in global health research in Africa. Therefore, mechanisms that could minimise the impact of these disparities, prevent exploitation of Africa researchers and populations could be the way forward.

It has been suggested that the negative impact of power disparities in global health research collaborations and its potential role in concerns of exploitation, could be minimised through appropriate governance mechanisms (Lee and Mills, 2000, Pratt and Hyder, 2016, Pratt and Hyder, 2017, Winickoff, 2008). In this thesis, I will explore issues of justice-related ethical issues in genomics research and biobanking consortia in Africa. I will unpack the structural inequalities that inform and shape genomics research in Africa, the impact that these inequalities have on genomics research in Africa, and how the inequities could be addressed through governance.

The overall aim of this study is to propose a governance mechanism for genomics research and biobanking in Africa[2]. To achieve this, I put forth the following specific objectives:

1. Identify principles, values and norms that can promote justice and fairness in genomics research and biobanking in Africa

[2] Africa is used in this thesis in more generic form. But that is not to say that it is a homogenous society. The continent enjoys lots of diversity including genetic, cultural and religious diversity. A more appropriate phrasing will be "certain African societies" in order to give room for this diversity.

2. Propose a principles-based governance framework for genomics research and biobanking in Africa that links its policies to the promotion of justice;
3. Investigate how the governance of genomics research and biobanking projects in Africa have considered concerns of justice and fairness;
4. Explore the views of key stakeholders on fair and just governance mechanisms for genomics research and biobanking in Africa.

Normative practice oriented bioethics approach was used to achieve the study objectives. This involved different methodological approaches, both conceptual and empirical. Since governance should ideally be informed by principles, values or social norms that are considered morally relevant for all persons involved in a shared activity (Hufty, 2011), I will start by identifying principles that could be considered relevant by all stakeholders in genomics research and biobanking projects in Africa. The principles will be identified through a conceptual or normative analysis of different global health justice and governance frameworks using the convergence approach. The framework's principles will then be tested through empirical scientific methods, mainly following the reflective equilibrium approach. This was to ensure that the governance mechanism actually addresses actual governance challenges of genomics research consortia and that it is not too abstract. First, I will provide an overview of some genomics research consortia in Africa and the justice-related ethical issues raised by genomics research and biobanking in Africa.

1.2 Genomics Research and Biobanking in Africa: An Overview

Genomics is the study of the structure, function, evolution and mapping of the genetic material of living organisms. It is a science that enables health researchers to elucidate how genes interact with each other and with the environment (non-genetic factors) and how this may impact on the health of individuals or populations (Burgner et al., 2006, Segal and Hill, 2003, Weatherall et al., 1997). Genomics research differs from most types of health research in that it is often interdisciplinary in nature, involves the use of high-throughput technology and requires large sample sizes to yield statistically relevant results. The need for large sample sizes, diverse scientific expertise and technology, has led many genomics researchers to organise themselves into a consortium or network. A genomics research consortium will often have a common goal but with each project, within the consortium, investigating an objective that is complimentary to the overall goal of the consortium. The need for large sample sizes has also compelled research consortia to establish biobanks and genetic databases that will store biological samples and data from the different projects. It is hoped that the stored samples and research data will be used for future research studies (Meldrum, 1995, Nyika, 2009, Collins et al., 2003). At the time of sample collection, it is difficult to tell, in detail, the different types of studies that the samples will be

used for. Therefore, sample donors have to consent to future, unspecified, uses of their samples and data. Genomics is therefore changing more traditional forms of health research which involved a research team working mostly by itself on a defined research project, to more collaborative ways of working which requires: the storing of samples for future unspecified uses and the sharing of samples and data between researchers with the aim of expediting the generation of robust results (Nyika, 2009, Wright et al., 2013).

The human genome project (1990-2003) was the first large scale international genomics project (Collins et al., 1998). The aim of the human genome project (HGP) was to completely sequence and map the entire human genome. The HGP involved researchers from 20 institutions in six countries, namely: France, Germany, Japan, China, the United Kingdom and the United States of America. Three founding principles of the HGP are worth highlighting as they inform the discussions on the ethics of human genomics research and biobanking in Africa. Firstly, whilst the HGP was a US-based project, it was open to research collaborations with researchers from other part of the world. Secondly, all information on the human genome sequence generated from the HGP was to be made publicly available within 24 hours of its assembly. Thirdly, the data from the project was made freely accessible for use by researchers, from any part of the world, in both academia and industry. The goal was to have an all-inclusive project that will benefit from diverse expertise and approaches (Chial, 2008). Although the human genome project, did not realise its initial hope of accelerating the discovery of new treatments for genetic diseases, it was arguably the kick-starter of the genomics revolution (Chial, 2008, Collins et al., 2003).

Following the completion of the HGP, a number of collaborative international genomics initiatives have emerged in, each with a mandate to study and catalogue genomic variants from population groups around the world. However, very few of these studies have primarily focussed on population groups in Africa or involved African researchers as key players (Need and Goldstein, 2009, Rosenberg et al., 2010, Popejoy and Fullerton, 2016).

The international Haplotype Mapping (HapMap) project (The International HapMap Consortium, 2003) was arguably the first international research consortium to extend the human genomic revolution to Africa. It, involved researchers from Nigeria and Kenya, and collected human biological samples in both countries. However, by 2010, only four of the thousands of genome wide association studies (GWAS), had focussed exclusively on African populations (H3Africa Consortium, 2014, Rotimi and Jorde, 2010). To fill this gap, a number of human genomics research consortia have been established in Africa such as the African Genome Variation Project (AGVP); the Human Heredity and Health in Africa (H3Africa) consortium; and the Neuropsychiatric genetics of African Populations (NeuroGAP) consortium. Below, I briefly

describe three genomics research consortia in Africa that epitomises the characteristics of genomics research consortia in Africa.

1.2.1 African Genome Variation Project (AGVP)

The African Genome Variation Project (AVGP) was one the early population genomics studies to focus exclusively on African populations. It aimed to investigate how the structure of the African genome differs from that of populations of European descent with the outcome of suggesting a framework for human genetic research in Africa (Gurdasani et al., 2015). It also assessed the feasibility of using commercially available genotyping chips for genomics studies on African populations (Friedrich, 2015). AGVP was a collaboration with the African Partnership for Chronic Disease Research (APCDR) and received funding from the Wellcome Trust, UK.

Samples for the AGVP were collected from Kenya, Nigeria, Uganda, Ethiopia, Ghana, The Gambia, and South Africa (Gurdasani et al., 2015). Genotyping was mainly done at the Welcome Trust Sanger Institute, UK and the genetic data was submitted to the European Genotype Archive (EGA). Access to data from AGVP is restricted and requires approval by the data from the data access committee of the ACPDR.

1.2.2 The Human Heredity and Health in Africa (H3Africa) Consortium

A second genomics research consortium in Africa is the Human Heredity and Health in Africa consortium (H3Africa). H3Africa was established in 2010 with funding from the U.S. National Institutes of Health (NIH) and the Wellcome Trust (H3Africa Consortium, 2014). One of its core objectives is to enhance the ability of African researchers to apply genomics technology to improving health research in Africa (H3Africa Consortium, 2014). H3Africa projects cover a range of diseases and will involve the creation of regional biobanks and a bioinformatics network and an ELSI arm (H3Africa, 2013). It is anticipated that about 75,000 samples would be analyzed as part of H3Africa research activities(H3Africa Consortium, 2014). . All H3Africa projects are nested in African research institutions and led by Africa-based researchers. Like the AVGP, H3Africa has a major African partner- the African Society of Human Genetics (AfSHG).

Aliquots of all the samples collected from H3Africa projects will be stored in one of three H3Africa regional biobanks. Genomic and phenotypic data from H3Africa will be deposited at the EGA and access will be restricted, as is the case with the AVGP. Persons or groups wishing to access and use data and samples from H3Africa will have request for access through the H3Africa data and biospecimen access committee (DBAC). However, before data is sent to the EGA, it will be temporary archived at H3ABioNet for nine months (H3Africa Consortium, 2014).

1.2.3 Neuropsychiatric genetics of African Populations (NeuroGAP)

A third consortium of interest is NeuroGAP. The main goal of NeuroGAP is to "advance genetic studies on mental illness"[3]. NeuroGAP was formed in 2017 and has partners in four African countries (Ethiopia, Kenya, South Africa and Uganda). Its HIC partners include: The Broad Institute, Oxford University and the Harvard Chan School of Public Health (Stevenson et al., 2019). The consortium is funded by the Stanley Center for Psychiatric Research at the Broad Institute, USA.

NeuroGAP is organised into four broad arms, two research arms, one capacity building and the other focussing on ELSIs in the genomics of neuropsychiatric disorders. The two research arms are: NeuroGAP-Psychosis which investigates the genetics of schizophrenia and bipolar disorder; and NeuroDev which focusses on the genetics of childhood neurodevelopmental disorders). NeuroGAP-Pyschosis will collect saliva and phenotypic data from approximately 35,000 individuals with schizophrenia and bipolar disease, as well as from persons without a history of psychosis (control group), from sites in all four participating African countries (Stevenson et al., 2019). The second research arm, NeuroDev, aims to investigate genetic and environmental risk factors for neurodevelopmental disorders in African populations and will recruit a cohort of 5600 participants in Kenya and South Africa (de Menil et al., 2019). Aliquot of samples collected as part of NeuroGAP will be sent to the Broad Institute, USA, for genotyping, whilst the remaining DNA extract will be stored in a designated biobank in one the participating African countries (Stevenson et al., 2019). NeuroGAP also plans to deposit genomic and phenotypic data from its research project into a public database and/or the European Genome-Phenome Archive. Access to the data will be through a controlled mechanism.

1.2.4 Other genomics research and biobanking consortia in Africa

Besides the three genomics research and biobanking consortia presented above, other genomics research consortia have focussed on African populations but may not have the majority of the characteristics which we aim to highlight that is: funded by institutions in HICs; involves the establishment of biobanks; focuses on African countries only; and requires the export of samples and the sharing of data. For example, MalariaGEN is a multicounty international genomics network that involves a number of LMICs in both Africa and Asia (The Malaria Genomic Epidemiology Network, 2008). The Southern African human genome project, on the other hand, is funded by the South African government and made of South African based researchers only (Pepper, 2011). Bridging biobanking and biomedical research in Africa (B3Africa) consortium will

[3] https://www.broadinstitute.org/stanley-center-psychiatric-research/stanley-global/neuropsychiatric-genetics-african-populations-neurogap Accessed 29March 2019

not be collecting samples but will rather focus on building capacity for the management of biobanks. Table 1, below, provides a brief description of some of these genomics consortia in Africa.

Table 1: Brief description of other genomics research consortia in Africa

Consortia	Objectives	Participating Countries	Funding
The Southern African Human Genome Project[4]	• Build capacity for genomics research in southern Africa • Establish a regional biobank • Knowledge translation to improve human health	South Africa	Department of Science and Technology, South Africa
The Malaria Genomic Epidemiology Network (MalariaGen)[5]	• Investigate how human genetic variation affects the biology and epidemiology of malaria • Use knowledge generated to develop malaria control tools	Burkina Faso, Cameroon, Gambia Ghana, Kenya, Malawi, Mali, Nigeria Senegal, Sudan, Tanzania. Papua New Guinea, Sri Lanka, Thailand, Vietnam United Kingdom	Bill and Melinda Gates foundation Wellcome Trust, UK
B3Africa [6]	• Develop a cooperation platform and technical informatics biobanking framework between Europe and Africa. • Build capacity for the management of biobanks. Through the development of software, toolkits and ELSI frameworks for data sharing between Africa and EU member states	Nigeria, Kenya, South Africa, Uganda Austria, France, Sweden and a pan-European biobanking consortium	European Union

[4] Pepper, M. S. 2011. "Launch of the Southern African Human Genome Programme." *S Afr Med J* 101 (5):287-8.

[5] Malaria Genomic Epidemiology Network. 2008. "A global network for investigating the genomic epidemiology of malaria." Nature 456 (7223):732

[6] http://www.b3africa.org/?page_id=2 accessed 29th May 2017

1.3 Ethical Issues in Genomics Research and Biobanking in Africa

A common theme in the three projects described above (HGP; AGVP, H3Africa and NeuroGAP) is the sharing of samples and data. Data and sample sharing is fast becoming common practice in genomics research and has many benefits including: reduced cost for research, ease of reproducibility of study findings; and ease of reaching large sample sizes required for statistically significant results in genomics (Kaye et al., 2009). A number of funding agencies now have a mandatory data sharing policy backed by the argument that it allows for maximum use of limited research resources. It is therefore not surprising that sample and data sharing practices are now becoming a norm in global health research projects. However, it is backbone behind the macro justice-ELSIs that global health research consortia in Africa will have to deal with (de Vries et al., 2015c, Tangwa, 2017, Van Rinsum and Tangwa, 2004).

Although the flagship HGP set the pace for open data sharing in genomics research (data was made freely available within 24 hours), there has recently been some inertia by African researchers to share data without any restrictions (Bezuidenhout and Chakauya, 2018, Jao et al., 2015). For example, access to data from the AGVP, H3Africa, and NeuroGAP, will be restricted or controlled and in some cases, the data will only be available for controlled access months after it has been generated. . These four projects have more or less the same funders and similar goals, yet there are nuance differences in their data sharing requirements. A compelling question, therefore, is: why are there differences in data sharing requirements between projects with a shared goal and same funders? This could be due to different reasons, some related to a history of scientific imperialism in international health research collaborations in Africa, whereby researchers from HICs collected samples from African populations, shipped them out of the countries without any benefit to the local population or researchers (Okwaro and Geissler, 2015, Tangwa, 2017, Parker and Kwiatkowski, 2016). Sample and data sharing also raises issues of ownership of biological material, secondary uses of samples stored in biobanks and benefit sharing (Barchi et al., 2015, Lucas et al., 2013, Moodley et al., 2014). It is believed that these different ethical issues could be addressed through defining mechanisms for promoting justice and fairness in genomics research consortia in Africa (de Vries et al., 2015c, Musolino et al., 2015, Parker and Kingori, 2016, Chen and Pang, 2015).

1.3.1 Justice in Global Health Research

Justice is at the nucleus of numerous philosophical theories. Some prominent accounts of justice that are relevant for health research include: distributive justice (fairness of outcomes); procedural justice (fairness of method and processes); and retributive justice (retribution and

punishment of an offender). Whilst fairness is a common theme in all three accounts of justice, there are different constructs of what fairness entails. A dominant view is that proposed by political philosopher, John Rawls. In his account of *Justice as Fairness* (Rawls, 1985), Rawls discusses fairness in light of two principles: liberty and equality. The liberty principle states that every person has an equal right to basic liberties. The equality principle, on the other hand, forms the basis of distributive justice and states that all institutions and positions should be open to all persons irrespective of their social background, ethnicity or gender and when that is not the case, inequalities should be to the advantage of the worst-offs. Justice is also one of the four core principles of biomedical ethics (Beauchamp and Childress, 2001) and forms the centre of the ethics debates in global health research (London, 2005, Hunt and Godard, 2013, de Vries et al., 2015b, Pratt and Loff, 2011, Pratt and Loff, 2014).

Recently, there have been calls for global health research programs to promote the ideals of justice and several tools, such as the research fairness index and the research for health justice framework have been developed to guide global health programs seeking to promote global health justice (Benatar, 2001, Ijsselmuiden et al., 2010, Musolino et al., 2015, Pratt and Loff, 2011). These calls are based on concerns of exploitation of African populations in health research. The principle of justice has however received little attention in global health research compared to other principles like autonomy. This is not surprising given the historical development of research ethics and the multiple, complex and sometimes contrasting philosophical and social constructs of what justice entails. When the principle of justice has been invoked in health research, the discussions tend to center around: reducing global health inequities; allocation of research resources, exploitation of vulnerable groups; research priority setting; selection of research participants; fair research processes; research ethics review; research design, access to proven interventions; obligations of the different stakeholders in research; and standards of care. These ethical issues can be grouped under two (but interrelated) broad constructs of justice: micro-level justice and macro-level justice.

1.3.1a Micro-level justice in global health research

Micro-level justice focuses on individual-based perceptions of fairness such as: equality, need and merit (Rawls, 1971). Emphasis is on the needs of the individual and the relationship between individuals. In health research, macro-level justice issues will for example be those related to the researcher-participant relationship, such as: standards of care in research conducted in LMICs and access to proven intervention (Hawkins and Emanuel, 2008).

1.3.1b Macro-level constructs of justice.

Macro-constructs of justice focus on the needs of society, rather than individuals. It is therefore more about aggregate fairness to society as opposed to fairness to individuals (Brickman et al.,

1981). Macro-justice is concerned with: the structure and development of the social order and in encouraging people to participate in the development of their society and to have a voice in a social process. The assumption being that if people find a procedure to be reasonable and feel respected and validated, they are likely to judge the process as fair. In health and health research, macro-level concepts of justice will for example look at questions of global health inequities and the allocation of research resources.

1.3.2 Justice-related ELSIs in genomics research and biobanking in Africa

Recently, genomics research and biobanking consortia in Africa have seen an increase in funding for ELSI research. This is motivated, in part, by the need to address concerns of "extractive" research, mainly the exploitation of African researchers and study populations. Testament to this is a growing literature on the ELSIs of genomics research and biobanking in Africa, including questions around: appropriate informed consent models; informed consent comprehension; community engagement, secondary uses of samples and data, ownership of samples and data, intellectual property, benefit sharing, feedback of study findings, and equitable research collaborations (de Vries et al., 2011, de Vries et al., 2012, de Vries et al., 2017, Lairumbi et al., 2012, Lairumbi et al., 2011, Munung et al., 2016, Nyika, 2009, Ramsay et al., 2014, Tindana and de Vries, 2016, Wonkam et al., 2011). Some of these ethical issues are related to the principle of autonomy, others are issues of justice and fairness. Below, I highlight some of these ELSIs with a focus on those that are linked to the promotion of justice and fairness.

1.3.2a <u>Secondary uses of samples and data for the benefit of African populations.</u>

Population genomics research thrives on collaborative research networks and the sharing of samples and data. This is partly due to statistical requirements for large sample sizes and a need for diverse scientific expertise (Kaye et al., 2009, Green et al., 2015). Therefore, samples collected as part of research projects will likely be shared with researchers or institutions that may not have been involved in the primary research projects. For example, in some genomics research projects in Africa, such as H3Africa it is required that aliquots of samples will be sent for genotyping to institutions in HICs and some stored n biobanks for future, yet undefined research use. Also, genomics researchers are increasingly expected to deposit their research data into public databases, with the hope that this will allow for maximum use of research data.

Data sharing is now increasingly considered a professional and moral obligation for researchers (Choudhury et al., 2014). It is also fast becoming a default funding requirement by most funders of genomics research (Zawati et al., 2014, Hood and Rowen, 2013) . Open sharing of samples and data has numerous benefits including: the potential to increase the social value of health research (Boulton, 2012); enhance the efficiency of the research enterprise; accelerate scientific discoveries and reduce research costs (Vines et al., 2014, Pisani et al., 2010).

Despite the above mentioned benefits, data and sample sharing raises a host of ELSIs in Global health research (Bull et al., 2015, Rappert and Bezuidenhout, 2017) and in genomics research in particular (de Vries et al., 2015a, Kaye et al., 2009, Parker et al., 2009). Firstly, population genomics studies in Africa often involves research collaborations, some of which go beyond national borders, therefore adding to the complexity of how samples will be accessed and used (Budin-Ljøsne et al., 2014, Lucas et al., 2013, Moodley and Singh, 2016). Secondly, the export of research samples from LMICs to HICs, has been major point of contention in global health research programs and the leading reason for fears bio-exploitation under the guise of global health research (Nienaber, 2011). Thirdly, there is little genomics research capacity in Africa, therefore some African researchers have expressed concerns that they may not be able to make downstream uses of samples in biobanks and the data generated from genomics research in Africa (Munung, 2016, Bull et al., 2015, Mulder et al., 2017). This leads to the question of whether samples collected from ongoing genomics studies in Africa and stored in biobanks for future research uses will eventually be used to investigate the pressing health needs of African populations. The same applies for genetic data generated from these projects and stored in genetic databases, or if the biobanks and databases would serve as a global research resource only, without due consideration on how use of the samples and data would benefit African populations. In case of the latter, one may then arguably say that African populations stand the risk of being exploited for the benefits of people in other parts of the world. Some initiatives and funding agencies have devised different ways by which concerns around exploitation and data sharing could best be addressed. For example H3Africa has adopted an "embargo" period during which data generated from consortium projects could only be used by the primary researchers even when it has been deposited in the public database. The European Union in developing the FAIR principles (Findability, Accessibility, Interoperability and re-usability) also puts more control of the data with the primary control of the data with the primary data generators (Wilkinson et al., 2016), a model which may also appeal in scenarios where fears of exploitation exist.

1.3.2b <u>Ownership of samples and data</u>

Data and sample sharing raises important questions around control and ownership of samples and data (de Vries and Pepper, 2012, Pepper et al., 2018, Barchi et al., 2015, Moodley et al., 2014). This has broader implications for access to samples and data and for the translation of research findings (e.g. intellectual property). Discussions on ownership of samples and data are complex and there is little guidance on who can make claims to ownership of genetic information or biological material. An example is the recent dispute over ownership of samples collected during the 2014 Ebola outbreak in Liberia, Sierra Leone and Guinea, where researchers from the three West African countries have registered complains that local researchers are not able to access samples that were shipped to the USA, United Kingdom and South Africa, following the

outbreak (Freudenthal, 2019). Neither do the local researchers have knowledge on how the samples and data are being used. However, the report by Freudenthal, 2019, shows that a laboratory in Europe is currently commercialising strains of Ebola virus extracted from the samples. The three West African countries have since written to the laboratories in Europe and the US to reassert their ownership of the samples and by extension, the right to information and decision making on use of the stored samples. Similar concerns of ownership have been raised in the USA (O'Brien, 2009) and Indonesia (Fidler, 2007). These examples demonstrate, first-hand, how claims of ownership may lead to a downstream desire to control how samples and data are used.

Debates on ownership of samples and data have led to the terminology of "custodianship". Custodianship is about assigning caretaking responsibilities of data and samples to an individual or institution. A custodian has the responsibility of providing oversight ensuring fair access and use by all stakeholders whilst and recognises the contributions of the sample providers (Yassin et al., 2010). Proponents of the custodianship model argue that it promotes transparency, fairness to human research participants and shared accountability among all stakeholders (Yassin et al., 2010). Ownership, on the hand, is informed by legal or symbolic attributions (Bjorkman, 2007). Therefore, ownership of samples and data may be ascribed to either: the sample providers; the researchers who generated the data; the institutions hosting biobanks; or the governments of the countries where the samples were collected. However, irrespective of who claims propriety rights over samples and/or data, the concern is that any stakeholder that retains ownership rights may hitherto have profound influence in decisions regarding sample and data use, in ways that prioritize their own interests sometimes at the expense of scientific advancement that may benefit the global population. In the custodianship model, stakeholders will have to decide on who has caretaking responsibilities for samples and data and how the entity would: promote fairness; ensure that there is maximum use of samples and data; uphold transparency and accountability (Winickoff and Winickoff, 2003, Fullerton et al., 2010, Yassin et al., 2010).

There are suggestions that global health research programs that plan to share samples and data should identify an independent body/individual that could serve as custodian of samples and data (Yassin et al., 2010). Ownership rights, on the other hand, may be shared between researchers, research participants and the research institutions providing oversight of samples and data (O'Brien, 2009). However, these discussions are yet to be extended to the ELSI discourse in genomics research in Africa. Although in some recent publications (Pepper et al., 2018, Yakubu et al., 2018), custodianship and ownership are used simultaneously with a seeming preference for custodianship.

1.3.2c Benefit sharing

Benefit sharing is *"the action of giving a portion of advantages/profits derived from the use of human genetic resources to the resource providers to achieve justice in exchange, with a particular emphasis on the clear provision of benefits to those who may lack reasonable access to resulting healthcare products and services without providing unethical inducements"* (Schroeder, 2007). Benefit sharing is a benchmark for ethical research in LMICs (Emanuel et al., 2004). It is embedded in the principle of justice (Beauchamp and Childress, 2001). It is also considered one way of building trust and promoting reciprocity between researchers and study communities (Knoppers, 2000). For example in 2007, the Indonesian government refused to share, with the WHO, avian influenza samples that were collected in Indonesia, a decision that shocked the global health community, as the samples were to be used for the development of an influenza vaccine. Indonesia had refused to share samples because it had been informed that an Australian pharmaceutical company was to use the samples and data to develop a vaccine, yet there were no clear plan for ensuring access to the vaccine by the people of Indonesia and other LMICs (Fidler, 2007). This caused an international outrage with many LMICs, including Libya and Nigeria, supporting Indonesia's position (Vezzani, 2010, Hammond, 2009, Franklin, 2009). This highlights reciprocity-based expectations in global health research. Also, there was a breakdown of trust between Indonesia and the WHO leading to reluctance to further share samples. Indonesia then created a database for sharing genetic sequences which requires secondary users to consult with the primary researchers before they submit any publication or Intellectual property agreements arising from use of the data.

Despite the importance of benefit sharing in advancing the ideals of justice in global health research, there are conceptual and practical challenges to the implementation of benefit sharing (Hugo Ethics Committee, 2000, Lairumbi et al., 2012, Schroeder et al., 2005, White, 2007). A question that stands out is: what constitutes a benefit in global health research. Empirical studies suggest that benefits could take the form of: access to healthcare; research capacity building; access to proven interventions; technology transfer; infrastructural development; and the provision of social amenities to study communities (Lairumbi et al., 2012, Munung, 2016). These different forms of benefits aim to advance justice at both the micro and macro-level. But it is debatable if benefit sharing should focus on individual needs or broader social issues that pre-dispose populations in LMICs to exploitation. Whether benefit sharing advances justice at the micro or macro-level, one may argue it is more about ensuring that populations who bear the risk of research should also share in the benefits (Schroeder et al., 2005, Hugo Ethics Committee, 2000). The discourse on benefit sharing will therefore benefit from explorative and conceptual studies that seek to identify what principles, values and norms justify benefit sharing arrangements and how it could be best implemented.

1.3.2d Intellectual property (IP)

A convoluted ELSI in genomics relates to "innovation" arising from genomics research and whether or not such innovations are permissible for patenting or intellectual property. There are several cases (successful and otherwise) of researchers or institutions that have applied to patent DNA sequences or genomics related inventions (Cook-Deegan and Heaney, 2010, Hopkins et al., 2006). Some of these include patents on: genes/gene sequences; methods for the isolation of DNA sequences; and healthcare products (e.g. diagnostic tests). There is also a movement against the patenting of DNA sequences, backed by arguments that: 1) DNA occurs naturally and therefore no one can claim to have "discovered" or invented them; 2) patents of DNA sequences will limit research and healthcare; and 3) DNA sequences do not meet legal requirements for patenting (NCOB, 2002). There are also parallel arguments that gene patents could fast track scientific discovery and innovation (Chandrasekharan and Cook-Deegan, 2009). However, a recent study showed that gene patenting has no important quantitative effect on scientific research and follow-on innovation (Sampat and Williams, 2019).

Whether or not gene patenting benefits or restricts scientific innovation, a point of interest for the global health justice debate is if the benefits from patenting will be evenly distributed (Smith et al., 2004). Patents work best where there is a healthy economy, which unfortunately, is not the case in most LMICs. Therefore, though patenting may serve as an incentive for the translation of genomics knowledge, if care is not taken, it may stifle innovation for health problems that are peculiar to LMICs. This may result in limited access to genomics medicine by populations in Africa, despite their participation in population genomics studies (Westerhaus and Castro, 2006, Correa, 2009).

The *UNESCO declaration on the human genome and human rights* (Article 4), states that "the human genome in its natural state shall not give rise to financial gain" (UNESCO, 1997). Whilst a number of regulatory regimens and patent offices have declared that gene sequences cannot be patented, there is still a wave of conflicts and controversies in Europe and the USA around patents and commercialisation in genomics (Kean, 2011, Cook-Deegan and Heaney, 2010). Genomics research and biobanking consortia in Africa would need to seek for solutions to the dilemma of IP, especially given the gaps in patent laws in most African countries.

The issuance of intellectual property and patents can incentivize translation efforts and encourage innovation. However, it will have to be done in such a way that as not to hamper research or limit access to proven interventions by populations in LMICs. That is, if patents and other IP rights are a necessity for innovation, an approach whereby access to innovation and other related benefits are made available for people in Africa would be need to identify in order to prevent a scenario whereby those provided the desired samples and data for understanding

human genetic variation and health, are unable to access the benefits of such research. This again raises issues of benefit sharing in population genomics research in Africa.

1.3.2e Fears of exploitation of African researchers and study populations

The final justice-related ELSI in genomics research and biobanking relates to fears of exploitation. Exploitation is a moral conundrum that occurs when an agent (person or group of persons) exploit another in a way that is considered morally wrong. Often, differences in power dynamics are critical for such exploitation to occur. (Brown, 2014).

The Kantian approach to exploitation describes exploitation as the harmful, merely instrumental utilization of a person's capacity for one's own advantage or for one's own ends. It goes beyond use to include harm. Morality is a central category in Kantian exploitation. In Kantian ethics, A exploits B when A gets a benefit from an interaction with B on a maxim that: reduces B's rational agency (even if this was done with consent from B); fails to acknowledge the needs of B as a rational agent (beneficence) and demeans or degrades B without preserving B's agency. Critics of the Kantian approach to exploitation argue that it is difficult to characterise what harm is and that the Kantian conception presupposes that exploitation is involuntary (Siegel, 2008) or degrades the weaker party (Wood, 2009), which may not necessarily always be the case.

More contemporary approaches to exploitation tend to base their argument on the idea that one may be exploited even with their voluntary consent and it may sometimes be mutually beneficial, even in cases of vulnerability. They rely on Wertheimer's conception of exploitation, that is: A exploits B when B receives an unfair level of benefits as a results of B's interactions with A (Wertheimer, 1999). The moral focus is on the level of benefits and not what B receives -This level of benefit must be fair. Fairness is characterised by the level of burden B bears as part of the interaction and the benefits that A and others receive as part of their interaction with B. Contemporary approaches to exploitation therefore seem to have adopted the fair benefits argument which are more justice-inclined. An unfair advantage occurs when A takes advantage of B's vulnerability and/or when A gains more than B (disproportionate benefit) as a result of their interaction (Ballantyne, 2005, Benatar and Fleischer, 2004).

Exploitation has been labelled a central inequity in international health research (Hawkins and Emanuel, 2008). There is also general consensus on the importance to prevent the exploitation of research populations in LMICs (Siegel, 2008). Interestingly, however, there is no consensus on what exploitation in health research entails, though there is some degree of agreement as to when it occurs. Exploitation in clinical research occurs when: a person's inability to provide consent is taken advantaged of; when the research does not address the health needs of the host population; and when post-trial benefits are not addressed by the sponsors of the research

(Emanuel et al., 2004, Ballantyne, 2005). When this happens, it can be said that the research sponsors have taken advantage of the vulnerability of study population to conduct research that offers them an unfair level of benefits.

Cases of exploitation of African researchers and study populations in global health research collaborations have been widely discussed (Tangwa, 2017, Okwaro and Geissler, 2015, Angell, 1997, Ballantyne, 2005, Freudenthal, 2019). These historical experiences have sometimes led to deep mistrust between HIC and African research partners; and a strong desire for equity in global health research collaborations (Munung, 2016, Parker and Kwiatkowski, 2016, Chu et al., 2014). A recent study showed that African scientists involved in genomics research in Africa had concerns of exploitation and expressed a desire for transparency, fairness and African leadership of genomics studies in Africa (Munung et al., 2017). The study also documented that African researchers wanted to be involved in decision-making processes with the hope that this will mitigate the potential of them being exploited.

Power asymmetries between LMICs and HICs have contributed to fears of exploitation of African researchers and study populations who are involved in global health research collaborations. For example, limited local funding for health research has seen African researchers enter into global health research collaborations on an unequal footing, mainly to access funds for research or to supplement their paltry salaries (Bhutta, 2002, Chu et al., 2014). This could give HIC researchers the advantage of pushing their own research agenda rather than prioritising the health and research needs of the African country. It is also claimed that funders and HIC researchers often dictate the research agenda in most global health programs and that sometimes their research agenda is very different from the needs of the LMIC where the study is being conducted (Sridhar, 2012, Chu et al., 2014). While global health research programs can be of benefit to both HICs and LIMICs, LMIC partners must be given a chance to participate in decision-making about key equity-oriented subjects such as research priority setting (Butrous, 2015, Pratt et al., 2016b). LMIC researchers must also ensure that studies conducted in Africa are responsive to the health needs of the study population. This is relevant for genomics research and biobanking in Africa where there is uncertainty on future use of samples stored in biobanks or data deposited in public databases. It will require that African researchers and other stakeholders be involved in decision-making on secondary uses of samples and data. Giving African stakeholders the opportunity to participate in decision-making making structures within global health research programs, has the potential to promote equitable and fair research collaborations (Munung et al., 2017).

In recent times, significant efforts have been made to address the moral wrongs of exploitation in global health research. In genomics research for example, a number of initiatives are in place to ensure that genomics research collaborations in Africa are fair and equitable (de Vries et al.,

2015c, Parker et al., 2009). There is no doubt that this has changed the way some global health programs currently operate on the continent and could possibly has led to significant changes in how African researchers approach global health research collaborations. However, the discussion has mainly leaned towards protecting African researchers from exploitation, with little being said about the possibility of exploiting African research populations. One of the few documented cases of exploitation of study populations in genomics research in Africa is that of the San people, where there are claims that although genomics studies on this indigenous African population would be of benefit to humankind as a whole, the study participants and community felt had been exploited by the researchers (Chennells and Steenkamp, 2018). The reasons for this vary including concerns that scientific publications from a particular study had reported information that was far removed from what it had primarily seek to address, and which could stigmatise the SAN people. Also, there were claims that the researchers persistently refused to meet and discuss the content of the consent forms. The San community considered this a show of disrespect by the researchers. This subsequently led to a series of conversations on the ethics of genomics research on indigenous populations resulting in the San code of research ethics (SASI, 2017). The code insists that before any health research is carried out in the San community: the protocol must be designed together with the community; there must be meaningful consultation with the San people; the project must provide in-depth information on the benefits of the study to the San people; and have a defined benefit sharing arrangement. The code also states that research on the Sans must be aligned to their local needs and aim to improve the lives of community members. Other recent examples were concerns of exploitation have been voiced by study communities include: the use of samples collected from Ebola patients by laboratories in Europe without the population being informed that their samples were to be used for research or in the development of a commercial product (Freudenthal, 2019). Also, sex workers in Kenya have pointed out that their contributions to research have not been rewarded in full (Andanda and Lucas, 2007, Schroeder and Lucas, 2013) and therefore requesting for: meaningful involvement in research processes, inclusion in decision-making in research projects were they are involved; a code of conduct for researchers; and more practical benefits from the decades of studies that they have been part of (Gosling, 2017, Tukai, 2018).

Based on the examples above, the possibility of exploitation of African researchers and study populations could be minimised through: prioritising research that is aligned to the health needs of study populations, identifying benefit and benefit sharing arrangements, building capacity for genomics research, having meaningful engagement with study communities; involving study communities and African researchers in decision-making; African leadership of research projects and transparency.

1.4 Study Rationale

It is undeniable that data and sample sharing would have to occur within a system that promotes high ethical standards (Kaye et al., 2009). This is important given markedly visible inequalities in health and health research between HICs and African countries, as well as concerns of exploitation and extractive research.

Genomics research and biobanking consortia in Africa will undoubtedly have to address ethical issues related to: secondary uses of samples and data; exploitation; ownership of data and samples; benefit sharing and intellectual property (Chen and Pang, 2015, Bull et al., 2015, de Vries et al., 2015c, Tangwa, 2017). To this effect, some genomics research and biobanking consortia in Africa have set up governance structures that would look into, on a case by case basis, the ethical issues raised by secondary uses of samples and data. However, it remains unclear how fair processes for access and use should be designed; and what principles or values should guide such processes.

A number of authors have proposed different ways or approaches by which concerns of inequities in global health research could be possibly addressed, including: the research for health justice framework (Pratt and Loff, 2014); and the human development framework (London, 2005). These frameworks, which were principally designed to advance justice in clinical research, have been applied to health systems research in LMICs (Pratt et al., 2016a, Pratt and Hyder, 2017, Pratt and Loff, 2013). However, global health research goes beyond clinical research to include other forms of research such as: biomedical research; social and behavioral studies; epidemiology; implementation research; and genomics research amongst others. Some of these research types involve the use of novel technology, or requires procedures that are different from traditional scientific practice and which may challenge the usual day-to-day research ethics discourse. A good example is genomics research. Genomics research and biobanking in Africa is taking place amidst fears that genomics may widen global health inequities (Pang, 2002, Singer and Daar, 2001b, Newport and Rotimi, 2009, Van Rinsum and Tangwa, 2004). This is not only because it is conducted in a part of the world that disproportionately bears the global burden of disease and that suffers from abject poverty (Tangwa, 2017) but also because it raises unique ELSIs compared to other forms of global health research (de Vries et al., 2011, Nyika, 2009, Wonkam et al., 2011). A key question that has emerged in the bioethics discourse is whether genomics will improve the health of world's people or if it will widen the technology gap between LMICs and HICs thereby worsening global health inequities (Singer and Daar, 2001b). With the recent influx of externally funded genomics research and biobanking initiatives in Africa, these questions need to be further explored not only for primary research studies but also for studies that would eventually use data and samples from African genomics studies.

Equally, genomics research and biobanking consortia in Africa are operating amidst a climate of strong fears of exploitation of genomics researchers in Africa as well as study populations (Munung et al., 2017, Van Rinsum and Tangwa, 2004, Wonkam et al., 2011, Chennells and Steenkamp, 2018). There is also a historical context to exploitation of African researchers in global health research collaborations (Annas and Grodin, 1998, Ballantyne, 2005, Hawkins and Emanuel, 2008, Okwaro and Geissler, 2015, Tangwa, 2017, Jentsch and Pilley, 2003). With the rise in externally funded and collaborative genomics studies in Africa, it is therefore important to explore the different ways by which genomics research and biobanking consortia in Africa could further the ideals of health justice and minimise the exploitation of study populations and African researchers. A keen look at the different ELSIs suggests that power and economic disparities between LMICs and Africa, as well as global health inequities, are the main stirrer for a majority of the macro-level justice-related ELSIs in genomics research and biobanking in Africa.

There are also broad perceptions that governance will be a tool for addressing macro-level justice ELSIs in global health research (Lee and Mills, 2000, Pratt and Hyder, 2016, Pratt and Hyder, 2017, Winickoff, 2008). This is because the majority of these justice ELSIs are due to power and economic differences between HICs and LMICs. Therefore, effective governance mechanisms that: articulate health equity oriented goals, minimises the influence of more powerful stakeholders in decision-making; and that sets out the responsibilities of all stakeholders, is more likely to foster the promotion of justice in genomics research and biobanking consortia in Africa. This thesis seeks to fill this gap by proposing a principles-based governance framework for genomics research and biobanking in Africa. We hope that such a framework would appeal to the broad range of stakeholders involved in genomics research and biobanking projects in Africa. To develop the governance framework, we used a variety of methodological approaches, including both conceptual and empirical analysis.

1.5 Thesis outline

In this study, we explored how the ideals of justice could be advanced in genomics research and biobanking in Africa, with a focus on governance. Specifically, we explored how genomics research and biobanking projects in Africa should be governed such that it promotes the ideals of health equity and justice. To do this, we embarked on a conceptual analysis of justice theories, as well as empirical research that captures existing governance of genomics research programs in Africa. I started with a conceptual analysis of two accounts of global health justice and a normative analysis of the African indigenous mora theory of Ubuntu. This led to the identification of principles that could guide the governance of genomics research in Africa. Following the identification of these principles, I proposed a principles-based (or conceptual) governance framework for genomics research and biobanking in Africa. To test if the proposed framework

will meet the needs of genomics research programs in Africa and how it could be implemented, I used two empirical bioethics methods (reflective equilibrium and the convergence approach) and qualitative research methods (case study, document analysis and in-depth interviews). The empirical data was used to check the frameworks requirements for areas of divergence and to revise accordingly.

This thesis reports on the conceptual and empirical work that was conducted. It is divided into eight (8) chapters:

Chapter 1 (the present chapter) sets the stage for the conceptual and empirical work. It includes: a brief description of genomics research and biobanking consortia in Africa, with the goal of highlighting unique characteristics of population genomics research in Africa. I argue that these characteristics of genomics research raise justice- ELSIs (also briefly described) which could be addressed through governance.

Chapter 2 is a presentation of the conceptual methods and analysis that were used to identify principles that could inform the governance framework. . This involved a conceptual analysis of three governance accounts: shared health governance; global governance for health; and the African moral theory of *Ubuntu*. Using the convergence approach, I identified key principles that could advance the ideals of justice and fairness in genomics research in Africa. These were then used to propose a principles-based governance framework for genomics research and biobanking in Africa.

Chapter 3 presents the principles-based governance framework for genomics research and biobanking in Africa, based on the principles that were identified in Chapter 3. The framework makes recommendations on how the principles could be operationalized. The aim is to have a framework that is not far removed from practice, yet grounded in theoretical principles.

Chapter 4 is a description of the empirical methods that I used to test the principles-based framework, mainly the reflective equilibrium approach. It involved a case study (H3Africa consortium); document analysis of H3Africa governance-related documents; and one-on-one in-depth interviews with stakeholders in genomics research and biobanking in Africa who are involved in governance processes or have in the past been involved in the development of H3Africa governance policies.

Chapter 5 is one of two chapters that report on the results of the empirical work described in Chapter 4. It is a presentation of the content analysis of H3Africa governance

documents. The interpretation of the analysis is partly informed by my experience as a student within the H3Africa consortium.

Chapter 6 is the second of the two result chapters. It reports on the in-depth interviews that were conducted with stakeholders in genomics research and biobanking in Africa. The analysis is supported by quotes from the interviews.

Chapter 7 presents the points of divergence between the principles-based framework and the empirical data. It also indicates revisions that will be made in the framework. The chapter ends with a description of how the principles-based framework could be applied to the justice-related ELSIs that were described in Chapter 1.

Chapter 8 is the last chapter. It is a summary of the outcome of the entire study. It includes a brief discussion of the study outcome; suggestions for future research; and the limitations of this study. I[7] conclude the chapter with a brief explanation of the impact of the study.

1.6 Researcher's Positionality

A good part of my postgraduate research (M.Sc. and PhD) work was nested in the H3Africa consortium. As an H3Africa funded postgraduate student, I have observed and sometimes been involved in the development of some H3Africa ethics policies.. Also, one of my supervisors was once the chair of the H3Africa ethics and regulatory issues WG. In her role as chair of the WG, she led the development of some H3Africa policies. She is also part of the H3Africa steering committee. We therefore knew first hand, persons who have been involved in developing governance for genomics research and biobanking in Africa and who were likely to provide an informed perspective on the justice-related ELSIs. We relied heavily on this knowledge and experience to select potential interviewees for this study, to give context to the problem under study, and analyse and interpret the empirical data.

I received a PhD student stipend from an H3Africa funded project. I do not however consider that this had a significant impact on the work reported in this thesis, as the funders were not involved in any part of the work from the design of the study to the interpretation of the empirical data. Neither have the funders been presented with any parts of these work for comments. I however, acknowledge that by receiving PhD support from an H3Africa project, it may have, to a limited extent had some salient and unintentional bias in the interpretation of the empirical aspects of

[7] "I" as used in this thesis, refers to the student.

the work. This was minimized by having a co-supervisor who has never been involved in H3Africa programs and who checked the interpretation of the results for any possible clues to bias

1.7 Research Ethics Clearance

Research ethics clearance (Appendix 1) was obtained from the University of Cape Town, Faculty of Health Sciences Research Ethics Committee (HREC REF: 548/2016). This approval was obtained in August 2016 and renewed annually (until data collection was completed).

1.8 Summary of Chapter

Recent years have witnessed a heightened discourse on ethical issues in global health research in Africa. This is accompanied by a noticeable shift from concerns about the burdens of participating in research to questions of justice and fairness (Varmus and Satcher, 1997, Ijsselmuiden et al., 2010). This shift is nowhere more evident than in genomics research and biobanking in Africa where many of the key ELSIs go beyond individual participants, to include broader issues of justice and fairness. A challenge for genomics research and biobanking in Africa is to create conditions whereby African researchers can feel confident that samples and data entrusted in their care will be used appropriately, and that decision-making processes for their use are sufficiently transparent and accountable (de Vries et al., 2011). One way to achieve this is through governance. The research leading to this thesis principally aims to address this gap.

Chapter 2: Towards a Principles-based Governance Framework for Genomics Research and Biobanking in Africa

Power and economic disparities between LMICs and HICs, as well as global health inequities contribute enormously to the exploitation of African Stakeholders involved in global health research in Africa. They also contribute substantially to the justice-ELSIs in genomics research in Africa. Therefore, mechanisms that could minimise the impact of these disparities, prevent exploitation of Africa stakeholders and build trust between all stakeholders, could be the way forward. In attempting to distribute power between stakeholders, and by extension resources and benefits, it will be advantageous to first identify shared values, norms and principles that should ideally inform the actions of all stakeholders. This is because if persons involved in a joint activity agree to abide by certain norms, principles, processes or concepts, then is there is likely to be a shared sense of fairness and equity amongst them (Gomez-Dants and Frenk, 2015, Kumar et al., 2016, Benatar, 2001).

The impact of power disparities and its potential role in exploitation can be minimised through governance processes that are informed by shared values (Lee and Mills, 2000, Pratt and Hyder, 2016, Pratt and Hyder, 2017, Winickoff, 2008). Governance is about principles, norms, values and institutions by which policies and decisions are made, implemented and enforced (Hufty, 2011, UNDP, 1997). It is also about managing power relationships within a given society (UNESCO, 2009). This makes governance an appropriate approach to addressing macro-level (society level) justice issues in genomics research and biobanking in Africa.. This thesis seeks to develop a principles-based governance framework for genomics research and biobanking that could provide guidance for navigating the macro-level justice-related ELSIs in genomics research and biobanking consortia in Africa.

In this chapter, I present the methodology that I used to identify the principles that could inform the governance of genomics research and biobanking in Africa. This involved a conceptual analysis of two theoretical accounts of global health justice and governance, and the African moral theory of *Ubuntu*. Drawing on empirical evidence from global health research projects in Africa, I also highlight what some of these principles could mean in practice. The overall goal is to identify principles or values that could guide the way genomics research and biobanking consortia in Africa address the macro-level justice ELSIs that I described in chapter 1: the

exploitation of African researchers and study populations, access and secondary uses of samples and data; ownership of samples and data; benefit-sharing and intellectual property.

I start the chapter by explaining why effective governance for genomics research and biobanking is important. I then describe the different approaches that we used to identify principles and values that can inform the governance of genomics research and biobanking in Africa. This involved a conceptual analysis of: two accounts of global health justice and governance; and the African moral theory of Ubuntu. Principles and values that were identified using the convergence approach. I conclude the chapter with a list and definition of the principles that we consider important, based on the theoretical analysis.

2.1 Governance of genomics research and biobanking in Africa: Why is it important?

The rich human genetic diversity in African populations is a rich research resource for studies aimed at identifying rare gene variants and their role in health and disease (Gurdasani et al., 2015, H3Africa Consortium, 2014). It is therefore not surprising that there is a systematic increase in population genomics studies in Africa, a good proportion of which involve researchers and funders in HICs. Many of these projects also have a biobanking component and require that researchers store an aliquot of their samples in biobanks; send some of the samples to laboratories in HICs for sequencing, and deposit the genetic data from their projects in public databases. Samples stored in biobanks as well as the associated clinical and genetic data may be used for research and/or innovation purposes by researchers from around the world.

The success of population genomics studies depends on: the availability of large samples sizes; huge amounts of funding, and the availability of diverse scientific expertise required to perform genomics analysis. It is therefore common nowadays for genomics research projects to organise themselves into a network or consortium. By organizing genomics research projects in the form of a consortium, researchers and other stakeholders could make maximum use of limited resources, easily achieve statistically significant sample sizes and share expertise in ways that would be impossible for single projects, given Africa's limited resources and capacity for genomics studies in Africa (Pang et al., 2003).

Despite the benefits of organizing into a consortium, fears of exploitation of African researchers and study populations involved in population genomics research remain a major concern (Munung et al., 2017, Upshur et al., 2007, Chennells and Steenkamp, 2018, Moodley and Singh, 2016) and would arguably come up in any ELSI debate on the ethics of genomics research in Africa. Similarly, genomics research and biobanking in Africa is taking place amidst a high disease burden, limited scientific capacity, and low public and private investment in health research,

therefore making African researchers and populations prone to exploitation by their collaborators in HICs (Wonkam and Mayosi, 2014, Tangwa, 2017, Benatar, 2002). Genomics research and biobanking consortia in Africa cannot afford to neglect these inequities and should put in place mechanisms to minimise the negative effects that such inequities may have on the bigger goal of genomics research in Africa- to prevent a genomics divide between HICs and Africa. A genomics divide between HICs and LMICs would likely widen global health inequities[8] (Newport and Rotimi, 2009, Singer and Daar, 2001b, WHO, 2002).

Exploitation in global health research is often associated with inequities in resources, research capacity and technological ability between Africa and HICs (Hawkins and Emanuel, 2008, Tangwa, 2017). There is no doubt that limited or no access to local funding makes African researchers vulnerable when they engage in global health research collaborations. For example, African researchers, as a means of professional survival, sometimes engage in research collaborations on an agenda different from their local health priorities or personal research interest (Kok et al., 2017). Whilst this may be beneficial for their professional development and the financial viability of their institutions, it may be not be contributing to improving the health of the global poor (Wolffers et al., 1998). In addition, the technological and research prowess of their HIC collaborators often mean the terms of collaboration are set by the HIC partner. When this happens, it can lead to avoidable tensions such as: fears of exploitation of African researchers and study populations, frustrations around not being consulted when research projects are designed; the absence of African voices in decision-making processes; and African researchers not being treated as equals by their HIC collaborators (Hawkins and Emanuel, 2008, Nordling, 2012, Munung et al., 2017, Tangwa, 2017), all of which have been expressed in genomics research in Africa (Munung et al., 2017, Munung et al., 2018, Parker and Kwiatkowski, 2016, Staunton et al., 2018). It has been suggested that these tensions could be addressed through fair and equitable governance mechanisms (Chen and Pang, 2015, Parker and Kingori, 2016, WHO, 2002). Hence, the need for a governance framework for genomics research and biobanking in Africa that addresses ethical issues that arise due to structural inequities in health and health research between HICs and African countries. This chapter describes the methodological approach we used in developing a governance framework for genomics research and biobanking in Africa.

[8]Genomics has been described as revolutionary biotechnology and the future of medicine. However, genomics research is extremely expensive and there is little evidence yet, that it will have significant health benefits for the global population commensurate with the amount of spending or if it will be “social bubble', analogous to the economic bubble where investment in genomics may end up with a negative cost-benefit ratio (BALL, P. 2010. Bursting the genomics bubble. *Nature: International Weekly Journal of Science.* 31 March 2010 ed.). This broader justice-related question, though not discussed at length in this thesis, is crucial in discussions around the genomics and global health inequity.

2.2 Methodology: A convergence approach to identifying key principles for the governance of genomics research and biobanking in Africa

Governance is a set of principles, norms, rules and decision-making processes around which the expectations of actors involved in a specific activity converge (Hufty, 2011). It is also the complex mechanisms, processes, relationships and institutions by which stakeholders engaged in a particular activity express their interests; exercise their rights and obligations; and mediate their differences (UNDP, 1997). Regulation and laws form part of governance. However, with the exception of international law, regulation and laws are fragmented and intended for use by the nation states that articulated them. Governance is broader in scope and includes principle, values and standards considered as good practice across nations or population groups (Shaw et al., 2005). Therefore, developing a governance framework requires identifying a principles and values[9] that may guide the operations between groups of people who share a common objective. To identify principles that could inform governance of genomics in Africa in ways that promote justice and fairness, I did a conceptual analysis of three theories of governance. The principles adopted for use in the framework were identified following the convergence approach.

2.2.1 The Convergence Approach

The convergence technique is a research method that entails comparing relevant theories and conceptual approaches with the overall aim of identifying points of convergence and divergence; and then pulling together the points of convergence to propose a practical solution to a problem (Pound and Campbell, 2015). The advantage of this method is that it leads to practical solutions that are less likely to be contentious, compared to solutions that are developed from a single theory (Bailey et al., 2015, Krubiner and Merritt, 2017). The convergence approach requires: 1) identifying theories that maybe relevant in addressing a moral question; 2) doing a meta-synthesis of the selected theories with the view of identifying points of convergence and overlap; and 3) using the common principles (points of convergence or overlap) to propose how the moral problem may be practically addressed.

[9] It may be important at this stage to define principles, values and norms. Principles are beliefs or rules that govern the behaviour of an agent. They are collectively agreed upon by society, and serve as a moral compass for behaviour. Principles tend to be concrete and provide almost immediate and very straightforward answers to ethical questions. Values, on the other hand, are standards of behaviour. Like principles, values can also give direction on how to address a moral problem. They are however less rigid than principles, and sometimes form the foundation of most principles. (For a detailed description, see Schroeder et al 2019, In Equitable Research Partnerships: A Global Code of Conduct to Counter Ethics Dumping. Cham: Springer International Publishing.

2.2.2 Identification of theories of justice that could inform the governance of genomics research and biobanking in Africa.

The moral problem that this thesis seeks to address is: how can the ideals of justice and fairness be advanced in genomics research and biobanking projects in Africa? In the introductory chapter, I argued that one effective way could be through governance. To develop a governance framework for genomics research in Africa, I interrogated different accounts of global justice and governance and to find a convergence or overlap of different principles considered relevant for global health partnerships. This is because theories of global justice provide a moral structure of what ought to be done to achieve fairness and equity at a global level (that is beyond nation state). Considering, that global health research has been linked to the promotion of health justice (Benatar, 2001, Gostin and Friedman, 2013), and that most of the justice ELSIs are linked to inequities (power, resources and health) between HICs and LMICs, theories of global health justice will be a favourable starting point.

There are different definitions and theories of global justice (Pogge and Moellendorf, 2008, Shapcott, 2011). However, in its most simplest form, global justice can be defined is a component of international relations that focusses on the moral obligation of the global rich to the global poor (Shapcott, 2014). Going by this definition, theories of global justice can be grouped into three broad categories: cosmopolitanism, communitarianism, and neo-realism. Cosmopolitanism views individuals as members of a single moral society and stresses on the need for individuals to detach from local or national affiliations and act as global citizens (Kleingeld and Brown, 2014). Communitarianism, on the other hand, is premised on the ideology that a person's social identity is moulded by their community, therefore shared communities values should be at the centre of moral judgement (Nussbaum, 2003). Neorealism emphasises the sovereignty of the state and the relationship between states in addressing global inequalities (Slaughter, 2011). These three approaches to global justice are the basis for the majority of theories of global health justice (Stapleton et al., 2014).

Global health justice is concerned with: avoidable and unfair disparities in health across global population; and the obligations of nation states to address global health inequities. The desire to address health inequities has led to the articulation of different accounts of global health justice (Gostin and Friedman, 2013, London, 2005, Ruger, 2011, Stapleton et al., 2014). These theories debate issues related to who has moral responsibilities for addressing global health inequities (Ruger, 2012c, Stapleton et al., 2014). To this effect, there is some conceptual work, albeit minimal, that seeks to link global health justice to governance. Some of these include: global governance for health (Gostin and Friedman, 2013, Gostin and Mok, 2009, Gostin et al., 2011) and shared health governance. To develop a governance framework for genomics research and biobanking in Africa, did conceptual analysis of these two dominant accounts of global health

justice and governance. This was informed by three main reasons. Firstly, their development takes into account power differences between LMICs and HICs and the impact that it has on global health partnerships. Secondly, these accounts link the promotion of global health justice to governance and therefore propose values or principles that could promote justice and fairness in global health consortia. Lastly, shared health governance (SHG) has recently been applied to the governance of global health research (Pratt et al., 2016a, Pratt and Hyder, 2017).

Developing governance also requires taking into consideration the values and cultures of the society where it will be applied. Considering that we are developing governance for genomics research conducted in Africa, I wanted to look at values that are common to populations across Africa and which could inform governance. I found the African philosophy of *Ubuntu* to be appealing. A number of African philosophies or theories of social justice exist (Kagame, 1976, Nyerere, 1968, Ramose, 1999, Verharen, 2008, Wiredu, 2006). However, I opted to use *Ubuntu* for a couple of reasons. Firstly, it has recently emerged in ELSI discussions on the governance of genomics and biobanking in Africa (Yakubu et al., 2018). Secondly, it is not only a moral theory, it embodies values, principles, and notions of traditional African justice and governance (Letseka, 2014), which are key elements that we seek in developing a governance framework. Thirdly, it has been used to inform organisational governance in traditional African societies (Khomba et al., 2013, Nzimakwe, 2014). Lastly, the *Ubuntu* philosophy is widespread across sub-Saharan Africa (Metz, 2007).

In the remainder of this chapter, I will: 1) provide a description of the three theoretical governance accounts; 2) highlight the principles promoted by each of them; 3) identify points of convergence between them and 4) use these points of convergence to select principles that could inform the promotion of justice in genomics research and biobanking in Africa.

2.2.2a Global Governance of Health (GGH)

Global Governance of Health (GGH) is a collection of norms, practices and institutions that collectively shape the health of the world's population (Gostin and Friedman, 2013). It was developed in response to major challenges faced in the governance of global health, including the impact of power differentials between LMICs and HICs; the economic power of selected stakeholders; and the ever changing landscape of global health (Gostin and Mok, 2009). GGH seeks to identify ways in which the disproportionate burden of disease borne by people in poor regions of the world could be addressed. It suggest that one approach to addressing global health inequities is to support research on diseases that are prevalent amongst the global poor or diseases, or diseases that are common globally but for which there are specific research and development needs in LMICs (Gostin and Friedman, 2013).

GGH: Strategies for promoting health equity in global health programs

GGH puts forth three strategies for addressing global health inequities: health systems capacity building; health priority setting; and stakeholder engagement (Gostin, 2007, Gostin, 2008). These three strategies are described below.

Capacity building: Capacity building should be at the centre of any global health program. This is because by building the capacity of health systems in poor countries, global health programs will be empowering local health systems to better respond to the health needs of their population. In GGH, the recommended approach to capacity building is one that follows a bottom up approach, whereby poor countries are allowed to, based on empirical evidence, identify their capacity building needs whilst international agencies support them to address the needs.

GGH further recommends three approaches to capacity building: 1) international agencies should make long term commitments to build health systems capacity in poor countries; 2) poor countries should take responsibility for identifying their capacity building needs; and 3) global health programs should measure the success of capacity building efforts. The last approach necessitates monitoring and evaluation of capacity building activities. Since GGH links the promotion of health justice to global health research, this would require that global health programs support research capacity building in LMICs. Obligations for research capacity building are assigned to both LMICs (to identify needs) and HIC stakeholders, (provide long term support for research capacity building).

Health priority setting: in developing GGH, the authors argue that one of the reasons why global health programs have repeatedly failed in their mission to reduce global health inequities is because do not often align their programs to local health needs. GGH then recommends that LMICs take responsibility for identifying their health priorities and that international assistance should be directed towards those priorities. Ideally, health priorities and that this should ideally be informed by epidemiological parameters such as morbidity, disability and mortality rates. GGH also advocates for global health programs to invest in health research on diseases that are: a major burden to LMICs; diseases with a global burden but for which research in LMICs is required; or major causes of structural inequalities in health between population groups (Gostin and Friedman, 2013, Gostin and Taylor, 2008). Based on international law, GGH assigns the responsibility of identifying health priorities in LMICs to national governments. However, like with capacity building, it recommends that when states are unable to define local health priorities, international agencies have a moral obligation to assist them in identifying these priorities and to then direct support towards local priorities. In the context of global health research, this would require that LMICs articulate their health research priorities and that resources for global health research should be directed at the identified priorities.

Stakeholder engagement: The last modality for GGH is stakeholder engagement. This is based on the observation that there is a lack of coordination and harmonisation of the activities of the global health actors, leading to fragmentation and duplication of efforts. Considering that the number of global health actors have proliferated in recent times, each with their own agenda, GGH recommends that all stakeholders, through a process of engagement and consensus driven dialogue, should agree on an approach to solving a particular global health problem. Such an approach should include the involvement of marginalized populations in policy development and evaluation; and should seek to identify and design comprehensive interventions aimed at helping LMIC populations to overcome barriers that prevent them from enjoying good health (Gostin et al., 2013).

GGH-Recommended norms for good governance

Besides recommending strategies for global health programs, GGH also suggests key norms and/or principles that should guide the governance of global health programs. These norms/principles include: Honesty, transparency, deliberative decision-making, efficiency, accountability and monitoring and evaluation (Gostin et al., 2010, Gostin et al., 2011).

Honesty: GGH does not define honesty. Neither does it state concisely how the honesty principle may advance the ideals of global health justice. However, other works by (Gostin and Mok, 2009, Gostin, 2008), link the honesty principle to transparency, truthfulness, open governance, free flow of information and civic participation.

Transparency: Transparency in GGH is considered hallmark for good governance. It is linked to honesty and discussed more in terms of truthfulness. Just like the honesty principle, transparency is likened to activities such as: open governance, free flows of information and civic participation (Gostin, 2008). GGH recommends that: decision-making processes are open and comprehensible to all involved; that there is the free flow of information amongst stakeholders; and that information on the activities and processes of global health partnerships be made freely available. This recommendation is based on observations that there is limited transparency in global health programs, both at the level of decision-making and communication. Transparency in decision-making is important for purposes of accountability, as it allows stakeholders to understand the reasons for decisions and to appeal such decisions when necessary.

Efficiency: As stated above, one of the major challenges to global health as identified by Gostin and colleagues is the lack of coordination between global health stakeholders involved. This lack of coordination has led to: missed opportunities for collaboration; increased cost; and the fragmentation and duplication of global health activities. Based on this, GGH recommends a governance structure with a coordinated architecture both at the global and local level with

detailed targets and concrete plans for all stakeholders. This would require defining a shared goal and also stating the responsibilities of each different stakeholder towards achieving that goal. GGH therefore calls for global health programs to articulate benchmarks for success, identify indicators for measuring these benchmarks; and have mechanisms in place to monitor and evaluate if the goals of the program are being met. The efficacy requirement therefore calls for monitoring and evaluation of global health programs.

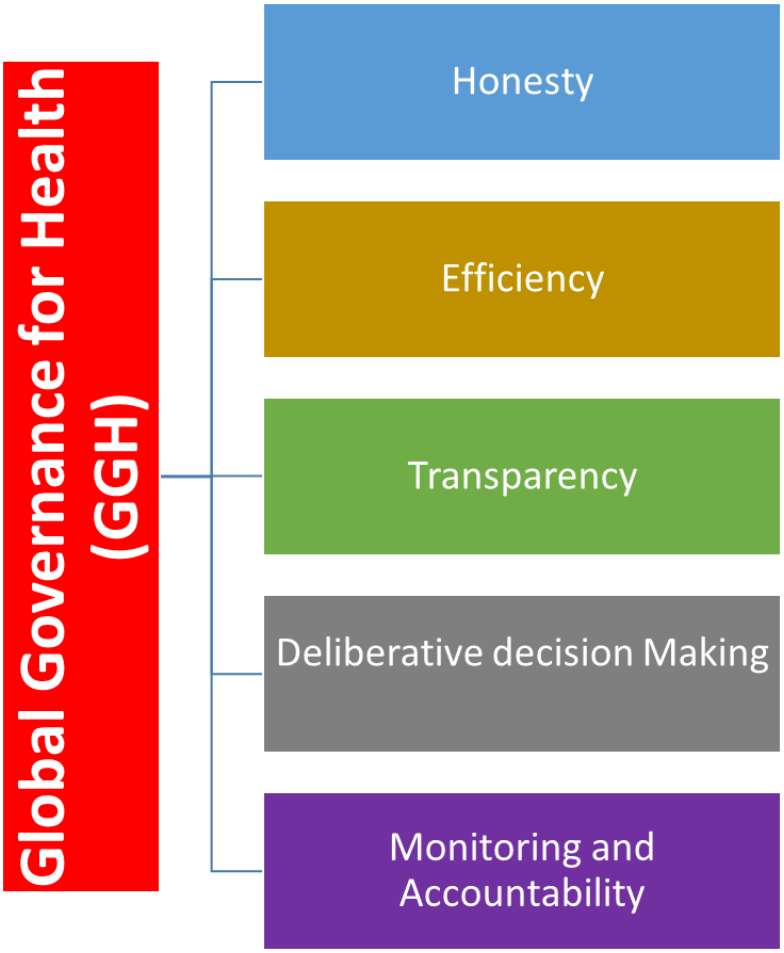
Deliberative decision-making: Deliberative decision-making is a key feature of GGH. The recommendation is that decision-making in global health programs should adopt a deliberative approach with all stakeholders genuinely listening to the views of others, especially those of disadvantaged groups (Gostin, 2014). This is also in line with the GGH strategy for stakeholder engagement, especially the involvement of disadvantaged groups in decision-making. Given that one of the challenges that led to the development of GGH is the difficulty in harnessing the efforts of the many global health actors, it may be best to first identify the different actors. Based on other works of Gostin (Gostin, 2007, Gostin, 2008), key actors in global health include: populations in LMICs, LMIC governments, HIC governments, non-governmental organisations, international health agencies, private industry, charity foundations, public/private hybrids, health researchers and the media. GGH recommends that these different stakeholders should be actively engaged in negotiation processes, debates and policy development and that this could take the form of active outreach programs (Gostin et al., 2010).

Monitoring and accountability: GGH requires that global health develop governance mechanisms that embody principles such as equity and accountability. For this to happen, global health programs should have: clearly defined objectives; transparent decision-making systems; mechanisms for information dissemination; and procedures for the monitoring and evaluation of the program's activities. This is because stakeholders will often demand clarity on how resources are being used towards the overall goal of reducing global health inequities. It is therefore important that global health programs identify clear equity oriented targets that: 1) will help improve health outcomes for all and reduce health inequities; 2) identify benchmarks and indicators for success; 3) have incentives and enforcement mechanisms (e.g. inducements, sanctions, mediation, and dispute resolution); 4) allow for interactive fora for all stakeholders and; 5) in the interest of transparency, make public the reasons for decisions (Gostin and Friedman, 2013). Accountability is therefore intertwined with the principles of efficiency, deliberative decision-making and transparency.

The participation of all stakeholders in decision-making is considered a key accountability mechanism in GGH. This is based on arguments that standard accountability mechanisms that are based on monitoring only are not politically neutral and may reinforce power inequalities

(Gostin and Friedman, 2013, Goetz and Jenkins, 2002, Ruger, 2011, Bruen et al., 2014). GGH therefore supports a wider and inclusive approach to decision-making and recommends that global health actors should provide reasons for the decisions that they make (Gostin and Mok, 2009). There are no suggestions on whether or not to apply sanctions when stakeholders fail to carry out their responsibilities, but there is the suggestion that sanctions could result in withdrawal of certain actors, leading to increased harm to the health of global poor mainly because most global health actors act on a voluntary basis (Gostin and Friedman, 2013).. Aware of this limitation, GGH advocates for an accountability system whereby poor and marginalised stakeholders are included in decision-making. This has the power of transforming traditional power dynamics such that powerful stakeholders having greater obligations of accountability to those with least political power.. Overall, GGH recommends an accountability mechanism that has clearer delineations of stakeholder responsibility, benchmarks and indicators of success, newly imagined incentives and sanctions; inclusive decision-making and effective governance structures at local and national levels. Figure 1 shows the different principles promoted by GGH.

Figure 1: Principles promoted by GGH



GGH: Global health institutions, stewardship and responsibilities

Besides suggesting strategies for promoting global health equity and principles that should guide the governance of global health programs, GGH also highlights the obligations of global health actors. In framing GGH, Gostin and colleagues begin by maintaining that nation states have the legal responsibility to provide essential health services to their populations. Therefore they assign the following responsibilities to national governments: securing the essential health package for their populations; setting national health priorities; effective governance through abiding to the norms/principles described above (Fig 1); and distributing health resources equitably (Gostin et al., 2010). However, the obligation to improve the health of the world's poorest and in reducing global health inequities is one that cannot be limited to specific nations, especially poor countries (Gostin et al., 2010). Therefore, richer countries have a responsibility to support poor countries to secure the minimum essential health package. Also, given that poor countries are usually those affected by the greatest disease burden but have limited resources to address it, GGH recommends that HICs support health systems development in LMICs.

Limitations of GGH

GGH lists honesty, transparency, effectiveness, deliberative decision-making, efficiency and mutual accountability as key principles for promoting justice and fairness in global health. However, it provides little information or guidance on the definition of these principles how they may be applied in practice. Equally, it is grounded in global law and assumes that there are legal structures in place for the implementation of global health programs, which is not always the case in LMICs.

2.2.2b Shared Health Governance (SHG)

A second theory of global health justice and governance that may provide guidance for developing governance for genomics research , is Jennifer Ruger's shared health governance (Ruger, 2011). Shared health governance (SHG) is founded on the theory of provincial globalism. Provincial globalism is an intermediate position between nationalism and cosmopolitanism (see section 2.2.2). Like GGH, SHG was developed in response to failure by global health actors to take up their roles and responsibilities (Ruger, 2012b). It also situates the problem of global health inequity as one that is due to the failure of global health actors to take up their responsibility and implement policies that effectuate the public moral norm of health equity (Ruger, 2012b). The public moral norm is a social norm, a shared conviction by any given society on the rightness of lack or wrongness on a particular idea or practice. It is about moral ideas set out by society on what ought to be favoured or disfavoured (Ruger, 2011). Public moral norms can serve as an authoritative standards in the quest for global health justice (Ruger, 2012c) and require individual and societal commitments (Ruger, 2006). Global health inequities are morally troubling and requires state and non-state actors to voluntarily identify and internalise norms that would facilitate to attainment of global health equity. This would require relying on theories of global health justice for principles, policies and tools, by which these inequalities could be addressed (Ruger, 2008).

Drawing on earlier works on the health capability paradigm (Ruger, 2010) and emphasising that health equity as a public moral norm, Ruger provides a road map for minimising global health injustices(Ruger, 2012a). Worthy of note is that in SHG, the public moral norm is considered as one that incorporates the interest on a person in relation to society, thereby suggesting a solidarity-based approach to global health. Also, SHG is grounded in global health law and therefore sees the world as a community and not a collection of individual nations (Ruger, 2008), thereby giving it a communitarian perspective. Although SHG is not related to conventional solidarity and not as communitarian as conventional solidarity (Ruger, 2011), it is "fundamentally synergistic with solidarity" in that it promotes solidarity at the global level, that is between

nations (DiStefano and Ruger, 2015)[10] and more of reflective solidarity (DiStefano and Ruger, 2015) than conventional solidarity. Reflective solidarity is the "mutual expectation of a responsible orientation to relationship" (Dean, 1998) and requires that consideration be given to individual expression instead of a "common conscience"(DiStefano and Ruger, 2015). That is to say the focus in reflective solidarity is more on the individual and self-regarding behaviour, than it is on society as a whole, compared to conventional solidarity which is about shared communal values.

In considering health equity as a public moral norm, SHG makes recommendations on the responsibilities, motivational aspirations, and institutional arrangements that are necessary for promoting justice and fairness in global health. These recommendations are broadly grouped into 5 principles (Figure 2).

Figure 2: Principles promoted by SHG

<u>Furthering the ideals of health justice (FIHJ)</u>

The first premise of SHG is that global health programs should aim to reduce global health inequities by improving the health of the global poor. SHG, like GGH, emphasizes the potential of health research to address global health inequities through the generation and translation of knowledge for the benefit of worst-off communities (Ruger, 2009). This could be achieved in three major ways: the creation of new interventions (vaccines, diagnostics etc.); management of

[10] See page 215

knowledge and information (health statistics); and the development research capacity in worst-off communities (Ruger, 2009). “Worst-off” can generally be defined as the most disadvantaged group. However, it is not exactly clear which population group or stakeholders SHG considers to be worst-off in the context of global health or how it is defined. The health capability paradigm however defines worst-off populations as those that experience substantial shortfalls in their health capabilities from the optimal level achieved worldwide (Pratt and Hyder, 2015). The optimal level is determined from population health indicators such as morbidity, disability adjusted life years (DALYs) and mortality.

The first approach to addressing global health inequities as suggested by SHG is the creation and distribution of knowledge generated from research. This could broadly be categorized as the translation of research findings. that could improve the health of worst-off populations (Ruger, 2012b).

The second strategy is health systems development in LMICs. This requires: providing technical and financial assistance to worst-off communities; coordinating the activities of the different actors (to minimise redundancies); empowering individuals and groups; and building research capacity in LMICs. SHG argues that the obligations for global health partnerships to build research capacity in LMICs is grounded in the principles of social justice and health equity (Ruger, 2012b). Citing the 10/90 research gap[11] as a major cause of health inequities, Ruger supports claims that there is an international obligation to help LMICs build their health research capacity, without which technological and scientific advancements may likely widen global health inequities (Ng and Ruger, 2011). As a result, there is an international obligation to support LMICs to build capacity for their research programmes and to access resources that could help them improve and maintain positive health outcomes (Ruger, 2007, Ruger, 2012b). These approaches have been elaborated in the context of health systems research in LMICs (Pratt and Loff, 2013).

Shared Sovereignty or shared decision-making

The next premise of SHG relates to decision-making. SHG depends on a group of individuals or institutions that come together to develop structures and procedures for decision-making; govern collectively; set standards for accessing success in a global health activity and for holding themselves accountable to one another and to society at large (Ruger, 2018). It also proposes that decision-making should be inclusive, deliberative and guided by acceptable public values and

[11] The 10/90 gap was coined by the global forum for health research and refers to the fact that less than 10% of funding for global health research is spent research for health problems that account for 90% of the global disease burden

moral norms. Despite these recommendations, SHG is silent on how shared sovereignty may be actualised in practice.

Shared Resources

The third premise is shared resources. SHG demands that the resources of a global health program should be distributed fairly based on the needs and wealth of each stakeholder. It also requires stakeholders to make efficient and effective use of resources that are allocated to them (Ruger 2011; Ruger 2012). This is similar to the efficiency requirement of GGH. There are three components to the shared resources premise. The first component requires contributing a fair share to the required resources. This demands that stakeholders contribute resources based on their level of wealth. The second component is on resource allocation and it requires that each stakeholder should receive resources based on their needs. The last component calls for stakeholders to use the allocated resources towards achieving justice in health. In the context of global health research, this entails allocating resources to the following: research agenda setting, research capacity strengthening; and research translation (Pratt and Loff, 2013).

Shared Responsibility

The fourth premise of SHG is shared responsibility. Global actors have an ethical commitment to reduce global health inequities. In developing SHG, Ruger makes the argument that global health actors are usually unaware of their roles and obligations, therefore it will be inappropriate to hold them accountable for unspecified responsibilities (Ruger, 2013). A view that is also put forth in GGH through the monitoring and accountability principle. Based on that argument, Ruger proposes that global health programs delineate the roles and obligations of each stakeholder (Ruger, 2012b, Ruger, 2013) and that this should be done following the functional requirements principle, i.e. based on the function that a stakeholder would typically assume (Ruger, 2011). Delineating the roles and responsibilities of all stakeholders creates a clearer lens for mutual accountability, legitimacy, the sharing of resources and possible recourse in cases where stakeholders fail to meet their responsibilities (Ruger, 2012c).

2.2.2c Mutual Collective Accountability (MCA)

The fifth, and final, premise of SHG is mutual collective accountability (MCA). MCA is an accountability mechanism that is appropriate for institutions that are multi-layered yet the different stakeholders have a shared goal (Ruger, 2012c). It obliges stakeholders in global health to identify: important outcomes and indicators for success; have standards on how resources will be used; and to develop a plan to ensure meaningful participation of all stakeholders in key decision-making for issues that affect them (Ruger, 2012b). All three requirements are also promoted by GGH in its monitoring and accountability principle (section 2.2.2a).

Given the many stakeholders involved in global health projects, Ruger contends that it may be difficult to tease out the separate responsibility of any given stakeholder but that all stakeholders should simultaneously be held to joint standards (Ruger, 2012c). But this will require that the different stakeholders agree on a goal and their respective roles and responsibilities towards achieving the set goal(s). Without such an agreement, it will be almost impossible to demand some degree of accountability from the different stakeholders. SHG therefore supports a peer review mechanism of accountability whereby stakeholders are answerable to one another and not to external actors, with the exception of the populations in which they work (Ruger, 2012b). Ruger later suggest that where necessary, some level of external accountability may be permissible, in which case stakeholders may be accountable to an international non–governmental organisation (Ruger, 2013).

Besides delineating roles and responsibilities of all stakeholders, MCA also demands that global health programs articulate standards for meaningful participation by all stakeholders, especially vulnerable groups, in decision making. This is particularly relevant for stakeholder groups that may be affected by the final decision. The recommendation to have standards for meaningful participation in decision-making, especially for disadvantaged groups, is similar to the monitoring and accountability requirement of GGH.

The last component of MCA is that global health programs should identify standards for distributing resources, with an emphasis on effective and efficient use of global health resources. The advantage being that increased accountability on the use of resources would ensure that resources are being used towards achieving shared equity oriented goals (Ruger, 2012c).

In summary, mechanisms for MCA should monitor the following indicators: goal alignment; level of resources; mutual understanding by stakeholders of the key outcomes; meaningful participation of all stakeholders; efforts made to engage vulnerable groups in decision-making; and the effective and efficient use of resources towards achieving global health equity (Ruger, 2012c, Ruger, 2012b, Ruger, 2013).

2.2.2d Limitations of SHG

SHG is a global health justice framework that suggests principles considered essential for global health justice. However, there is little information on how the different premises maybe actualized or implemented. But unlike GGH, SHG provides more details on the core principles and gives clues, albeit minimal, on how they may be implemented. For example there is little guidance on how the premise of shared sovereignty may be achieved besides stating, as part of the MCA requirement, that vulnerable groups should be properly engaged in decision-making. This makes the application of SHG to the everyday operations of global health consortia a bot challenging.

Overcoming some of the limitations of SHG

Based on Ruger's work on SHG and drawing on the work of political philosophers: Norman Daniels and Iris Young, Pratt and colleagues have championed work on applying the shared sovereignty principle to health systems research in LMICs (Pratt et al., 2016a, Pratt and Hyder, 2016, Pratt and Hyder, 2017, Pratt et al., 2016b). In doing so, they have developed standards for shared decision-making in global health research. Many of the recommendations they make are consistent with that suggested in GGH. Features of shared sovereignty as prescribed by Pratt and colleagues are presented below.

Deliberative decision-making

Deliberative decision-making is derived from theories of deliberative democracy (Chambers, 2003, Cohen, 2003). Proponents of deliberative democracy argue that humans are political equals, and therefore ought to, as a community, deliberate with one another and to reach an agreement (Dryzek and Niemeyer, 2012, Cohen, 2003, Rawls, 1993). In deliberative democracy, all parties that may be affected by a decision should be given the opportunity to: propose solutions to the problem under consideration; give reasons for their position; and listen and consider the solutions and reasons advanced by other stakeholders (Young, 2002).. At the end of a deliberative process, members of a group may not necessarily agree on the final decision, but their perception of the problem may change, based on the reasons provided by other stakeholders. The idea behind deliberative democracy is to be able to reach a conclusion that will considered fair by all. Four major standards for fair deliberative decision-making have been proposed by accountability of reasonableness (A4R), a prominent theory of deliberative democracy. They include: relevance; appeal/revision; publicity; and enforcement (Daniels and Sabin, 2008a).

The first standard for deliberative decision-making is relevance. Relevance demands that decisions should be based on the values and principles shared by stakeholders who may be affected by the decision (Daniels, 2000). A necessary step for the relevance condition is to identify stakeholders who may be affected by a particular decision. The second standard is appeal and revision and its premised on the idea that a fair decision-making process should allow for revision and improvement of decisions in light of new evidence or arguments (Daniels, 2000). The rationale for the appeal and revision standard is that it gives room for more engagement and in the process caters for stakeholders who may not have been involved in the initial decision-making process, or who may not have been clearly heard or understood, to dispute or approve the final decisions (Daniels, 2001). For this to happen, there should be procedures for challenging final decisions (Daniels and Sabin, 2008b). The third standard is publicity and it entails making final decisions and the reasons for them publicly available. This ensures that stakeholders understand

the moral basis by which final decisions are based (Daniels and Sabin, 1998, Daniels and Sabin, 2008b). It also has the advantage of improving transparency (Daniels, 2000). Publicity, and by extension transparency, could be practically implemented through open meetings, circulation of minutes, and the use of other open communication processes (Byskov et al., 2014). The last standard for deliberative decision-making is enforcement. It is about monitoring and evaluating decision-making activities to ensure that they are in line with the first three standards described, which are: relevance; appeal and revision; and publicity (Daniels, 2000). The enforcement standard allows for decision-makers to be held accountable for the decisions that they make (Daniels, 2001). The enforcement component of deliberative decision-making overlaps in many ways with the principle of mutual collective accountability (see section 2.2.2c).

Inclusiveness

The second component of shared sovereignty after deliberative decision-making is inclusiveness (Young, 2002). Deliberative theorists recognise that although participants within an institution should be considered political equals, societal norms and practices may influence the ability of some participants to influence political decisions. Also, more powerful participants generally tend to dominate decision-making and to skew the final decision in their favour (Rawls, 1993).

Inclusiveness does not only refer to including all stakeholders in decision-making. It extends to how and when they are involved. . Using the case of health systems research in LMICs, Pratt and colleagues suggest a framework for deep inclusion in decision-making in global health research (Pratt et al., 2016b). The framework proposes three criteria for ensuring inclusivity: breadth; qualitative equality; and non-elite representation. Achieving breadth requires including stakeholders with a wide range of relevant roles in decision making and ensuring that no one stakeholder group is disproportionately represented compared to the other. This is to minimise the possibility of any stakeholder group to dominate the decision-making process by virtue of their numbers. Qualitative equality, on the other hand, is about ensuring that each stakeholder group is not just represented but also has a chance, through reasoned argument, to influence the final decision (Young, 2002). For this to happen, all stakeholders should be given equal opportunities to: express their views; to respond to questions; and to ask questions to other participants (Cohen and Fung, 2004). The deliberations should also be structured in a way that minimises the impact of power disparities. Such an approach can create a sense of solidarity and increase trust amongst all actors (Valadez, 2018).

Equally important for inclusivity is the involvement of “non-elite” stakeholder groups when making decisions that affect them (Smith and Wales, 2000, Cohen and Fung, 2004). This is because the opinions of highly educated experts are frequently (and sometimes falsely) taken to be the shared premise (Young, 2002). High quality non-elite participation is a function of the time

of engagement and the degree of involvement (Pratt et al., 2016b), it is easier to achieve more engagement if non-elite groups are included earlier in the research process. Pratt and colleagues have suggested an approach to engaging non-elite groups in decision-making (Pratt et al., 2016b, Pratt et al., 2018) and this includes: shared decision-making; proposal sharing; and information feedback. In proposal-sharing, citizens make suggestions based on what they would decide if they had the power to make a particular decisions (Caron-Flinterman et al., 2005). In information-giving, citizens give their opinion on suggestions that have been provided by those who created the decision-making process. All three forms may take place at different phases of the study. Shared decision-making is thought of as the most desirable of the three, and is likely to take place in a collaborative partnerships. On the hand, proposal sharing and feedback of information are likely to take on a consultative format. Consultative decision-making involves soliciting the views of select individuals when making a particular decision, however the views of these individuals may or may not be taken into account when making the final decision (Arnstein, 1969). Usually, those consulted are often experts in the area of interest and in some cases may not be affected by the decision.

2.2.3 *Ubuntu*: Application of an African moral theory to the governance of genomics research and biobanking in Africa.

In the previous sections (2.2.1 and 2.2.2), I presented two accounts of global health justice and governance, namely GGH and SHG. However, an African perspective or moral thought will also be very important in framing discussions around justice and governance in genomics research and biobanking in Africa (Tangwa, 2017). This is because when proposing solutions to justice-related issues, it is important to do so in ways that are sensitive to local values, beliefs and practices.. In this thesis I seek to develop a governance mechanism for genomics research and biobanking in Africa. An African perspective to governance will be important in ensuring some degree of buy-in by the different stakeholders.

In this section, I describe the principles and values promulgated by an African indigenous moral philosophy, *Ubuntu*. I acknowledge that there are different African moral philosophies (Kagame, 1976, Verharen, 2008, Wiredu, 2006). However, I am interested in *Ubuntu* for two main reasons. Firstly, *Ubuntu* has in recent times emerged in ELSI discussions as an African moral theory that could inform ELSI discussions in genomics (Pepper et al., 2018, Yakubu et al., 2018). For example, it featured in discussions by the H3Africa WG on Ethics and Regulatory Issues though the group could not reach a consensus on the role of this philosophy at the time, (Yakubu et al., 2018). . *Ubuntu* also emerged in in the process of discussions on ethics governance of genomics research in South Africa (Pepper et al., 2018). Secondly, although the word *Ubuntu* originates from southern Africa, it is a Bantu philosophy with equivalent concepts in many sub-Saharan African communities (Dauda, 2017, Metz, 2007, Oppenheim, 2012, Ramose, 1999), and therefore its

principles are likely to appeal to populations across Africa. Thirdly, *Ubuntu* (and equivalent concepts) has been used foundation for governance in some African countries and corporate bodies (Nyerere, 1968, Nzimakwe, 2014, Khoza, 2012, Mbigi and Maree, 1995). I therefore envisaged that by exploring *Ubuntu* alongside other accounts of social justice and governance, we would be able to incorporate an African perspective to the governance of global health research in general and genomics research and biobanking in particular.

2.2.3a An African world-view of humanity[12]

Ubuntu is an African indigenous moral theory for humanness (Metz, 2007, Tutu, 2012, Ramose, 1999). It is the philosophical foundation by which African people think and act towards each other (Sulamoyo, 2010). The word *Ubuntu* originates from two *Nguni* languages, Zulu and Ndebele, and is captured in the phrase, *umuntu ngumuntu ngabantu,* which literally translates to: *A person is a person because of another person*. *Ubuntu* upholds the principle of solidarity and emphasises that members of a community have a responsibility to share, support and care for one another, so that each may achieve their full capability (Nzimakwe, 2014). The interdependence of the individual on her community is therefore at the centre of *Ubuntu* (Ramose, 1999, Dauda, 2017).

Equivalent concepts of *Ubuntu* exist in other communities in sub-Saharan Africa. For example, the Yoruba of Nigeria, express humanism in the phrase *Omoluwabi*, which literally means, *one who is of high integrity and probity* (Dauda, 2017). The Koms of Bamenda Cameroon say *wa ghi wul* i.e. *you are a person* (Tosam 2014). In Kiswahili, an East African language, it is termed *utu,* and is derived from an indigenous governing concept which advises that every action should be done for the benefit of the community (Oppenheim, 2012). Across the different cultures, one can arguably say that *Ubuntu* ethics is about value systems and social contracts of mutual respect, responsibility and accountability (Venter, 2004).

Ubuntu is a purely communitarian ethics and is said to be the way of life of African people (Biko, 1987, Mbigi and Maree, 1995, Mkhize, 2008, Ramose, 1999). Members of a community are expected to put communal values first before those of the individual (Callahan, 2003, Du Toit, 2005). The expectation is that the individual, though autonomous, is in a mediated relationship with his/her society and that communitarian values, such as reciprocity, trust and solidarity supersede individual choice (Tauber, 2002, Ramose, 1999). This communitarian conception of a person is what the phrase, *A person is a person because of another person* captures (Mbiti, 1968).

[12] It is again important to emphasise that whilst I write of Africa as if it is a homogenous continent, it is quite diverse culturally. However, the foundations of most African cultures, particular sub-Saharan Africa are arguably very similar if not the same.

It is an epistemology that begins with the community and then moves to the individual (Battle, 2009).

The values and principles promoted by *Ubuntu* have been applied to governance in different sectors including: business, conflict resolution, corporate management and education (Lutz, 2009, Mbigi and Maree, 1995, Msila, 2015, Shanyanana and Waghid, 2016). However, its application to health and health research remains minimal (Tosam et al., 2017). In the following paragraphs, I will tease out the values and principles promoted by *Ubuntu* that could inform the governance of genomics research in Africa. This is particularly relevant given recent calls for an African-informed governance for ELSIs in genomics research and biobanking in Africa (Pepper et al., 2018, Tangwa, 2017, Yakubu et al., 2018). The core principles promoted by *Ubuntu* are described, in general terms, below.

Solidarity

Solidarity is a key value in African communitarianism (Wiredu, 2000). Broadly, solidarity can be defined as unity based on shared values, objectives and standards (Prainsack and Buyx, 2012, Mbigi and Maree, 1995). It is a realisation that one's capability depends on others and the common good should be pursued rather than the individual good. *Ubuntu* is the capacity in African culture to express compassion, reciprocity, dignity, harmony and humanity to others (Nussbaum, 2003). Group solidarity is therefore a key aspect of *Ubuntu* and is central to the survival of a community (Mbigi and Maree, 1995). This transcends reflective solidarity promoted by SHG (DiStefano and Ruger, 2015) to include communal solidarity that promotes the flourishing of all members of a society, irrespective of their ideologies, viewpoints and personal values. Given that solidarity is a key principle in African communitarianism and that the two global health justice theories do not directly refer to solidarity, it is worth highlighting how this principle may apply to the governance of genomics research and biobanking, lest in becomes too abstract.

Solidarity is manifest in the ethics discourse in genomics research and biobanking in Africa in different ways. For example, empirical evidence shows that motivation to participate in genomics studies in Africa are often linked to a desire to contribute towards finding health solutions to the disease under study, as well as a desire of the research participant to know about their health status (Masiye et al., 2017, Tindana et al., 2012, Moodley et al., 2014, Ogunrin et al., 2018). Yet, even when it was done for the advancement of science, research participants have raised issues of benefit sharing (Moodley et al., 2014) and the desire to receive information on secondary uses of their samples and data (Ogunrin et al., 2018, Tindana et al., 2012, Igbe and Adebamowo, 2012). This will suggest that motivations to participate in genomics research and biobanking studies are grounded in reciprocity-based solidarity (supported by *Ubuntu*). Secondly, although studies have shown that there is a willingness amongst African researchers to share samples and data, there are guarded concerns around the exploitation of African researchers and research participants

that may hinder open sharing (Munung et al., 2017, Okeke, 2016, Wonkam et al., 2011). This has led to calls for genomics research in Africa: to be aligned with national health priorities; to adopt shared decision-making processes; to promote opportunities that will build trust amongst stakeholders; and to support research capacity building in Africa (Barchi et al., 2015, de Vries et al., 2015a, Moodley and Singh, 2016, Munung et al., 2017, Munung et al., 2018, Ramsay et al., 2014).

Reciprocity

The principle of solidarity is intertwined with the principle of reciprocity. Reciprocity is the awareness that that human interactions are generally contingent upon mutual exchange whereby people continuously give and receive as part of daily life (Metz, 2007). Reciprocity is forthrightly expressed in many African cultures and life is seen as mutual aid. It is for this reason that most African societies have an expression for the aphorism "*the right arm washes the left arm and the left arm washes the right arm*". Julius Nyerere captures reciprocity as such "*In our traditional African society, we were individuals within a community. We took care of the community, and the community took care of us. We neither needed nor wished to exploit our fellow men"* (Nyerere, 1968). *Ubuntu* highlights this interconnectedness and calls for people to be responsive to the needs of others, not necessarily in terms of the exchange of goods but through one's attitude to the community (Mkhize, 2008).. Reciprocity, in the African worldview, is therefore about expressing concern for the welfare of others. Like solidarity, the principle of reciprocity has not been widely discussed in global health research, therefore it may be important to give examples of how it could be applied to genomics research in Africa.

As stated in the section on solidarity, some empirical studies have shown that those who bear the risk of participating in genomics research and biobanking studies in Africa, do so on grounds that their samples and data would be used for future research to advance science and to find health solutions to certain diseases. Also, there is some level of expectation that as one contributes to a research cause, they will, in return receive some health benefits either individually or at the community level. Another relationship for which there are expectation of reciprocity is that between African researchers and secondary users of samples and data. There are concerns that African researchers who collected samples and data as part of primary studies may not be able to use the data as much as their counterparts in well-resourced settings (de Vries et al., 2015c, Munung et al., 2017, Walport and Brest, 2011). This ignites fears of exploitation leading to an inertia by African researchers to share samples and data. There is a need to balance the risk and benefits of sharing samples and data whilst taking into consideration the limited research capacity in LMICs. Many suggestions have been made including the need to build capacity for genomics research in Africa and to recognise the efforts of primary researchers and data generators (Bezuidenhout, 2018, Bull et al., 2015).

Reciprocity is about mutual relationships characterised by trust, respect, transparency, and shared responsibility (Mkhize, 2008, Nyerere, 1968). Trust is important in the relationships for which reciprocity is expected. For example between researchers/research institutions and research participant; and between data generators and secondary users of data (Merson et al., 2015). But being trustworthy requires that one takes responsibility for certain actions and these responsibilities will have to be defined and agreed upon by all stakeholders. SHG makes a similar recommendations with a preference for using the functional requirement principle in assigning responsibilities (See section 2.2.2b section "shared responsibility"). However, *Ubuntu,* like GGH, does not state how responsibilities should be assigned.

Deliberative and consensus decision-making

The third feature of *Ubuntu* is deliberative decision-making. Deliberative democracy has dominated decision-making in African traditional settings (Wiredu, 2002). An example is Nyerere's *Ujamaa,* where best practices for governance are likened to decision-making processes that involves community elders sitting under a tree and discussing freely until they reach an agreement (Nyerere, 1968). Consensus is key in decision-making in African settings and "*every person is regarded as a fountain of knowledge who has valuable things to contribute to society as a whole*" (Blankenberg, 1999). This explains the African saying: *"Knowledge is like a baobab tree; no one person can embrace it with both arms".* Collective decision-making is at therefore at the centre of an *Ubuntu* society and like in SHG, it is characterised by respect for each other, listening intently to others and making efforts to understand what others are saying (Msila, 2015). The advantage of collective decision-making is that it has the power to build trust and strengthen the communal spirit within a society.

The decision-making process in traditional African settings has also been described as participatory consensus (Ayittey, 2010) . It often involves town or community meetings e.g. *Indaba* (Zulus, South Africa), *Ama-ala* (Igbo, Nigeria) and *Durbar* (Northern Ghana). During these town meetings, an idea is put forth for discussion by a leader to the elders. Once the idea has been discussed by the elders, it is then opened up for discussion by the community. Usually the public is encouraged to speak and ask questions and this is followed by deliberations until a consensus is reached (indicated by hand-clapping and nodding of heads). In the African traditional system, governance is, as a rule, characterised by persuasion and consensus driven dialogue as opposed to majoritarian rule (Osabu-Kle, 2000, Wiredu, 2000). When it is difficult to reach consensus on a particular point, meetings are rescheduled and deliberations continue at a later stage until consensus is reached. Voting is avoided at all cost so as to prevent majoritarian rule and the oppression of minority opinions. In this way, consensus can be considered an expression of solidarity. That is, though we differ in our views, we choose to unite for the good of the community. This points to the aspect of reflective solidarity supported by SHG (section

2.2.2b). Even with the hierarchal nature of African traditional governance where certain groups (for example elders or the chief priest) could have more powers and therefore dominate decision-making, there are always mechanisms in place to ensure that every person has an equal chance to speak (Louw, 2001). In cases where agreement cannot be reached, the matter is dropped for a while to allow for more engagement (Horne, 2004).

Consensus as a decision-making procedure also requires, in principle, that each representative be persuaded, if not of the optimality of the final decision, but at least of its practical necessity (Wiredu, 2000). This is similar to the approach suggested in GGH and SHG that global health actors provide reasons for their decisions. Many Africanist writers have endorsed consensus decision-making as the sole normative paradigm through which the common good is obtained in the African value system (Ramose, 1999, Osabu-Kle, 2000, Wiredu, 2002). For example, in describing fair decision-making in traditional African settings, President Kenneth Kaunda states that "*In our original societies, we operated by consensus. An issue was talked out in solemn conclave until such time as an agreement could be achieved"* (Wiredu, 2006). This is to say the community will agree to proceed with a certain approach even if they disagree with the reasons (notion or morality) for adopting that particular approach. This has been described as the *willing suspension of disagreement* (Wiredu, 2000).

This approach to decision-making while beneficial has some disadvantages. For example, reaching consensus with a large group can be time consuming. However, many have argued that the length of time is often compensated for by a readiness to accept and implement decisions by all within a society (Ayittey, 2010).

Inclusiveness

Also of importance in African traditional system is representation. Two aspects of representation are important: the representation of all stakeholder groups (formal representation); and the representation of the will of all stakeholder groups (substantive representation) (Wiredu, 2000, Shanyanana and Waghid, 2016). Based on this classification, there can be formal representation without substantive representation, in which case a group is represented but their voices are not heard and taken into account. Substantive representation is what is considered a legitimate approach to decision-making in African traditional system (Osabu-Kle, 2000, Wiredu, 2000, Horne, 2004, Ramose, 1999). Also, to minimise the effect of one group having a disproportionate influence on decision-making, power is distributed between the different communal groups (Sesay, 2014).

The value of inclusivity is consciously encouraged and promoted in decision-making processes communitarian setting in and it is believed that inclusivity in decision-making embodies key

aspects of good governance such as: trust, transparency, accountability and equality (Burgess, 2017, Nzimakwe, 2014, Shanyanana and Waghid, 2016, Khomba et al., 2013).

Accountability

Accountability in *Ubuntu*-style governance accountability is seen more in terms of participatory governance and takes the form of going into a community and engaging with them, not just as key informants but also as agents of change who are capable of addressing concerns and issues that affect their community (Burgess, 2017). Reporting back to the community on shared activities is important but that should be done not just for the sake of reporting back but with the goal of receiving and implementing feedback from the community. In which case, a community meeting (Ayittey, 2010) could be used as vehicle for sharing information and receiving feedback from meeting participants. It is therefore about accountability to the different stakeholders, as is the case in SHG. There is however very little information in the literature on Ubuntu and accountability.

Trust

Another principle that is important in *Ubuntu* societies is trust. Trust is the expectation that one can rely on another person's words and actions and that the person has good intentions to carry out their promises (Bligh, 2017). It is a relational concept and has more meaning in a scenario whereby one party is vulnerable to the other. *Ubuntu* is based on a system of mutual trust and respect for members in a society. Trust is gained when there is respect and recognition of the contribution of all members of the community (Mbigi and Maree, 1995). In African cultures, trust is built through long-term consistency in words and actions (Ting-Toomey, 2012).

Figure 3 provides a representation of the principles and values espoused by *Ubuntu* and how they are all centred on solidarity as an overarching principle.

Figure 3: Principles promulgated by *Ubuntu*

2.2.3b ***Ubuntu* and Governance**

Ubuntu has several implications for governance. A number of African political leaders have appealed to its use or that of equivalent moral theories or concepts, in the development of national policies. An example is Julius Nyerere's, socio-political ideology, *Ujamaa* (Swahili for family-hood*),* whereby best practices for governance were likened to the custom of African elders sitting under a tree and having a free discussion on a particular dilemma or problem until they agree (Nyerere, 1968). Proponents of *Ubuntu* argue that institutions that reflect this manner of deliberativeness are undoubtedly democratic and consultative, and in many ways promote principles of justice and fairness such as: solidarity, reciprocity and mutual benefits (Khoza, 2006, Tutu, 2012).

Ubuntu also theorises a collective humanist existence, that is, *I am because you are*. That is not to say a person's responsibility is concealed through group effort. Rather, each person is expected to, while pursuing their own good, participate in community activities in ways that foster the common good (Lutz, 2009). Equally, values such as social cooperation, sharing, open society, transparency and deliberation are enshrined in African moral theories (Louw, 2002, Mandela,

2006, Nussbaum, 2003). It also emphasises the importance of open sharing and equitable use of resources in ways that had been agreed by the community (Khomba et al., 2013, Khoza, 2012).These principles have been successfully applied to the management of organisations in Africa (Khomba et al., 2013, Lutz, 2009, Mbigi and Maree, 1995), and may be extended to global health research.

Limitations of *Ubuntu*

The rationale for including *Ubuntu* as an African philosophy that could inform the governance of genomics research *was because* my aim was to develop a governance framework that is informed by African values, principles and norms. However, unlike SHG and GGH, *Ubuntu* was not developed to address challenges in global health and the application of some of its principles will require much wider discussion.

2.2.4 Points of Convergence and Divergence: *Ubuntu*, GGH and SHG

In analysing SHG, GGH and *Ubuntu,* five (5) principles emerged as common in all three theoretical accounts. These five principles are: shared decision-making, transparency, shared resources, shared responsibility and accountability. (Table 2).

Table 2: Points of convergence (and divergence) between GGH, SHG and *Ubuntu*

Principle	*Ubuntu*	GGH	SHG
Furthering the ideals of health justice (FIHJ)	Possibly	✓	✓
Honesty	Not included	✓	Not included
Solidarity	✓	Not included	Synergistic to solidarity (reflective solidarity
Deliberativeness	✓	✓	✓
Transparency	✓	✓	✓
Accountability	✓	✓	✓
Trust	✓	✓ (honesty)	Indirectly (through deliberative decision-making, transparency, accountability and shared responsibility
Shared resources	✓	✓(Indirectly: efficiency requirement)	✓
Efficiency	Not included	✓	Not included
Reciprocity	✓	Not included	Not included
Shared responsibility	✓	✓ (accountability principle	✓

Solidarity and reciprocity are directly promoted by *Ubuntu* only. However, as stated in section 2.2.2b, SHG is synergistic with solidarity. The principles of trust, efficiency and FIHJ are promoted in at least two of the governance accounts. The outliers are: solidarity, reciprocity and honesty. The first two are directly promoted by *Ubuntu* only and the last by GGH.

FIHJ appears in GGH and SHG but not in *Ubuntu*. This could be expected given that *Ubuntu,* as an African moral theory, does not primarily set out to address issues of global health. In contrast, SHG and GGH aim to address the ills of global health inequity. Nonetheless, *Ubuntu* advocates for communities to work together to advance the common good or a shared goal. Therefore, if it was construed within the confines of global health, *Ubuntu* will likely speak to furthering global health justice, given that *Ubuntu* is characterised by a deep sense of solidarity and consideration for others.

The principle of trust is not directly promoted by SHG. But in advocating for shared sovereignty, transparency, accountability and shared responsibility, SHG suggests that these different principles are essential in promoting trust between stakeholders. Also SHG is in line with the plural subject theory, a consciousness of unity amongst a group of individuals jointly committed to a shared objective (Ruger, 2011) and that trust is based on the reciprocity of others, i.e. the consciousness of unity.

The principles of honesty and efficiency are directly supported by GGH only. Efficiency is about effective use of research resources in ways that address the ills of global health equity. It is also about effective coordination of the different stakeholders to avoid duplication of efforts and that stakeholders are carrying out responsibilities assigned to them. It can therefore be linked to the principles of shared resources, shared responsibility and accountability. Honesty, on the other hand, is about transparency, free flow of information and civic participation in global health. It therefore speaks to the principles of trust, transparency and shared decision-making. The principles of honesty and efficiency would not be taken forward as they are related to principles that are found in all three theoretical accounts.

Solidarity and reciprocity are promoted, at least directly, by *Ubuntu* only. The principles of solidarity and reciprocity are intricately linked and it is sometimes difficult to talk about one without referring to the other. Although solidarity is not stated upfront as a component of SHG, Ruger considers reflexive solidarity as a compliment to SHG but noting that that unlike conventional solidarity, the focus is on the individual and not the community (DiStefano and Ruger, 2015). I had sought to provide an African voice to the governance in global health research. Despite the lack of outright convergence on the principles of solidarity and reciprocity, I included them in the framework as a way of ensuring that African values and principles are promoted in the governance of genomics research and biobanking.

Some of the principles are defined or described differently in the three accounts, but in ways that are complimentary. For example, in SHG and GGH, the equality of all stakeholders is important. *Ubuntu*, on the hand, recognises the class structure in most African communities but then highlights the importance of substantive representation, which is about giving equal voice of all members of the community by ensuring that the perspectives of the different groups (age, clan, social status) are taken into account during decision-making. Accountability is another area where there is a slight difference in the definition. GGH and SHG suggests that accountability could be achieved through monitoring and increased participation of all stakeholders in decision-making, and by clearly delineating the responsibilities of all stakeholders. *Ubuntu* speaks of accountability more in terms of participatory governance and the need to report back to communities, not just for the sake of informing them, but also to allow them provide feedback. In all accounts, however, inclusive participation and transparency are necessary requirements for accountability. All three accounts also support a peer review accountability mechanism (mutual collective accountability) whereby stakeholders are accountable to each other rather than to an external body.

Generally, most of the principles are defined or described in detail by SHG only (except solidarity, reciprocity and trust). GGH tends to give practical information on how the principles could be implemented, without necessarily defining the principle or providing sufficient information on what it entails. For example. GGH supports monitoring and evaluation as a means of ensuring accountability. However, it doesn't describe or define accountability. The same can be said for *Ubuntu* I will therefore adopt definitions provided by SHG and lean to the different accounts for practical ways by which they may be implemented. In the case of solidarity, reciprocity and trust, I will use the definitions from *Ubuntu*.

2.2.5 Principles adopted in the governance framework

Based on the convergence approach, I adopted nine (09) principles for use in developing the framework. These principles and their definition/description are shown in Table 3.

Table 3: Principles that will inform the development of a governance framework for genomics research and biobanking in Africa.

No	Principle	Brief description
1	Solidarity	Communal unity based on shared goals, values, responsibilities and standards Global health research should improve the health of all but should also address the health and research needs of the global poor
2	Reciprocity	Human interactions are generally contingent upon mutual exchange The expectation that as one contributes to a cause, then some health benefits will come back to them or to their communities
3	Furthering the ideals of health justice (FIHJ)	Global health projects should improving the health of people in poor regions and reduce global health inequities This includes prioritising the health needs of populations in LMICs; building research capacity in LMICs; and supporting the translation of research findings.
4	Shared sovereignty	Procedural justice is important Decision-making should follow a deliberative process Decisions should ideally be reached via consensus Democratic and substantive representation of all stakeholders i.e. giving equal voice to all stakeholders
6	Shared resources	Resources should be fairly distributed towards equity oriented goals. Stakeholders should receive a fair share of resources based on their needs
7	Shared responsibility	Responsibilities of stakeholders should be clearly delineated Assign responsibilities based on the functions they typically assume

8	Mutual accountability	Stakeholders should be simultaneously held to joint standards and must agree to their respective roles and responsibilities. Identify outcomes and indicators of success. Mutual understanding by stakeholders of the key outcomes of the project. Have standards on how resources would be used Develop a plan for meaningful participation of all stakeholders in decision-making, especially the participation of vulnerable groups Monitoring and evaluation of program goals.
9	Transparency	Decisions and activities of projects should be available to all stakeholders Free flow of information Civic participation in consortium's activities
10	Trust	The expectation that one can rely on another person's words and actions and that the person has good intentions to carry out their promises. A relational concept and has more meaning in cases whereby one party is vulnerable to the other. Respect and recognition of the contribution of all stakeholders

2.3 Chapter Summary

In this chapter, I presented the conceptual work leading to the identification of principles that could inform the governance of genomics research and biobanking in Africa. Two accounts of global health justice and governance (GGH, SHG) and the African moral theory of *Ubuntu* informed our conceptual analysis. Based on the convergence approach, A total of nine principles were selected for use in the developing a governance framework for genomics research and biobanking in Africa.

In the next chapter, I will propose a principles-based governance framework genomics research and biobanking in Africa. This framework will be based on the principles presented in Table 2. It also takes into account that most of the macro-level justice issues in genomics research and biobanking in Africa often evolve around the sharing of samples and data.

Chapter 3: A Principles-based Framework for the Governance of Genomics Research and Biobanking in Africa

Principles-based governance provides a common frame of reference on the values of by which decisions ought to be made or how institutions need to conduct themselves (Black et al., 2007, Honderich, 1995). Governance models that adopt a principle-based approach often have more latitude and flexibility (Laurie and Sethi, 2013) and serve more as pointers for the relevant values and norms that stakeholders ought to consider when designing and implementing programs.

In this chapter, I present a principles-based framework for the governance of genomics research and biobanking in Africa. The proposed framework is informed by GGH, SHG and *Ubuntu*. Based on the convergence approach, reported in the previous chapter, we identified nine (09) principles that could inform governance of genomics and biobanking. These principles include: furthering the ideals of health justice (FIHJ); solidarity, transparency, reciprocity, mutual collective accountability; shared sovereignty, trust, shared resources and shared responsibility. I presented a description of the different principles in the previous chapter (summarised in Table 3).

For each principle I provide make recommendations for its implementation. The aim is not to be too prescriptive, but rather to provide context on how the principles may be operationalised (Sethi, 2018). In proposing this framework, the assumption is that all samples and data would have been collected and stored with the informed consent of the research participants and that there are mechanisms in place to safeguard their privacy and confidentiality. Also, some of the principles and/or recommendations may apply to other forms of global health research.

3.1 Furthering the Ideals of Health Justice (FIHJ)

Genomics research and biobanking consortia in Africa should aim to further the ideals of health justice. This could be done through improving the health of populations in poor regions and reducing global health inequities. It has been suggested that the contribution of genomics to improving population health will occur in three inter-related steps (Collins et al., 2003): genomics to biology (elucidating the structure and functions of genes); genomics to health (translate knowledge generated to heath); and genomics to society (promoting the use of genomics to maximize health benefits and minimize harms). All three steps are key and may be embedded in genomics projects at different stages. However the impact that genomics research would have on global health inequities would depend on how they promote the three global health equity objectives which we described in chapter 2 (section 2.2.2a and 2.2.2b). The three equity oriented objectives include: research priority setting; research capacity building; and research translation

3.1.1 Research Priority Setting

Disparities in health and wealth between countries and limited resources for health and health research in Africa raises questions of justice and fairness in genomics research and biobanking in Africa (de Vries et al., 2015c, Munung et al., 2017). A common concern is the possibility of exploitation of study populations and that African researchers tend to work on the research agenda of their HIC partners rather than on local health priorities.

Establishing research priorities for genomics research and biobanking in Africa (including secondary uses of samples and data) can serve as a good approach to ensuring that limited research resources are directed to the health needs of African populations and that concerns of exploitation of African populations are minimized. Also, identifying research priorities for genomics research in Africa will help funders, researchers and policy makers to direct limited research resources towards health conditions that are likely to yield maximum public health benefits. It would also facilitate the transformation of a donor-driven research agenda to one that is driven by the health needs of study populations. However, the process for research priority setting would have to be guided by the following principles: transparency, shared responsibility and shared sovereignty (Pratt and Loff, 2014).

- Genomics research and biobanking consortia in Africa should prioritise diseases that: 1) are a major contributor to the disease burden in Africa; 2) has a strong evidence of genomics aetiology; 3) there is limited ability to modify exposure or risk factors through environmental or lifestyle changes and 4) diseases for which the use of genomics could have a high public health impact. This is because not all diseases or health conditions that are of a major cause of morbidity and mortality in Africa will necessarily need to be addressed using genomics.. Secondly, it will be ethically problematic to divert scare research resources to explore health conditions for which cheaper and more feasible options are likely to be successfully applied in resource limited settings. Epidemiological parameters such as mortality, morbidity and disability adjusted life years (DALYs) should serve as a guide for research priority setting for genomics research in Africa.

- At the initiation stage, genomics research and biobanking consortia should decide on the stakeholders that would be involved in identifying research priorities, provide reasons for including them in the process; and state the role of the different stakeholders. Ideally, it should include: funders, African researchers, healthcare providers in Africa, study population, African governments, as these different groups have a shared interest in driving a successful genomics research agenda in Africa.

- To minimise the influence of unequal power dynamics that may influence research priority setting in Africa in favour of more powerful stakeholders, the research priority process should be initiated and led by African stakeholders with the support of HIC partners and should follow a deliberative process. Where there is limited capacity, by African stakeholders to identify and set genomics research priorities, international agencies and professional organisations, such as the WHO should play a facilitative role by providing technical and financial support to African countries to help them identify their genomics research priorities.

- Funders should prioritise genomics research projects that are aligned with the health and health research needs of African populations or more generally, health conditions that would be of benefit globally but for which research on African populations is required. This applies to both primary studies and projects that will use samples or dataset from the primary studies.

- Data and biospecimen access committees (or the equivalent) should give priority for access to samples and data to research projects that are aligned to local research priorities.

3.1.2 Research capacity strengthening

Capacity building is one of the core ways by which global health research consortia may advance the ideals of global health justice (See sections 2.2.2a and 2.2.2b). The aim is to strengthen the capacity of African countries to independently conduct research on the health needs of their populations. Capacity building should be evidence-based and occur at different levels (project, institution and national level) over a long period of time to allow for African researchers to have the capability to conduct independent research. It may therefore involve: providing technical and financial assistance for genomics research in Africa; coordinating the activities of the different actors (to minimise redundancies); and empowering individuals and groups that are engaged in genomics research and biobanking in Africa.

- Research capacity building is key to achieving equitable research partnerships in Africa. Genomics research and biobanking in Africa should clearly articulate plans to build genomics research capacity in Africa. This should include capacity building for: researchers (junior and senior); research users (communities, healthcare providers, policy makers, etc.); and research institutions.

- Research capacity building should be evidenced-based and directed by the African partners. This will ensure that capacity building efforts are tailored to the needs of African partners, thereby supporting them to carry out research that is of relevance to their communities. Capacity building activities should be done in collaboration with local institutions and coordinated with the needs of the populations where the studies would be carried out. African partners should be given a greater voice in deciding what capacity building is required.

- African researchers should lead primary genomics research projects in Africa. This would mitigate the unequal influences that powerful partners may have on key processes such as decisions around research priorities, secondary uses of data and samples and resource allocation.

- The impact of genomics for study populations, lies more in how it would be used to improve health and healthcare of African populations. Genomics research and biobanking consortia in Africa should develop the capacity of African institutions, researchers and physicians in genomics medicine. . This will include: the training of medical geneticists, genetic counsellors; providing support for genetic medicine units; and supporting the development of interventions for genomics medicine in Africa.

- African governments should take responsibility for building their capacity in genomics research. Where they are unable to do so, funders, HIC researchers and other international agencies should support them through a long term commitment to build research capacity including more long-term research collaborations

- For projects that would use datasets from genomics studies conducted in Africa, funders and data and biospecimen access committees should prioritise resource allocation to projects that have plans to collaborate with researchers in Africa on a long term basis. This will ensure sustainability of genomics research in Africa

3.1.3 Research Translation

The most direct way in which genomics could impact on the future of medicine in Africa is through the availability of genomics medicine in healthcare settings in Africa. This would require the translation of research results to practical health interventions/policies (Collins et al., 2003, Khoury, 2003, Seguin et al., 2008, Singer and Daar, 2001b). Translation can sometimes come with the need to secure patents and Intellectual Property (IP) rights. Patents and IPs often serve as

incentives for promoting innovation in health (Eisenberg, 1990). On the other hand, it can increase the cost of health inventions, impose restrictions on research and development and impede the transfer of existing tools and technologies (Williams, 2010). Many African countries do not have the capacity to translate research findings and to support innovation in biomedical research and healthcare. For this reasons, genomics research consortia should develop mechanisms that would ensure the equitable distribution of knowledge and resources generated from the projects and how the knowledge from these projects would be used to support the development of interventions.

- Genomics research and biobanking consortia in Africa should clearly articulate a translation strategy for population genomics studies in Africa, including how they will promote translation of research results in ways that will benefit populations in Africa. In cases where an intervention is developed from the study, there should be mechanisms in place to ensure sustained access to the intervention

- Where genomics research in Africa leads to new knowledge that could refine health policy or practice, African researchers should liaise with healthcare providers, national governments and funders to advocate for such new knowledge to be incorporated into clinical care and practice.

- To facilitate the translation of research findings as well as the uptake of interventions by study populations, significant stakeholder engagement is required. Genomics research and biobanking projects should at early stages, design research, educational and stakeholder engagement programs to facilitate the training of healthcare workers, policy makers and the general public on genomics medicine. This has the potential to achieve a level of genomic literacy amongst stakeholders as well as facilitate the integration of genomics into healthcare.

- African researchers, research institutions (through patent offices), national governments and research participants should identify the kind of patents that would be acceptable for genomics research in Africa. Researchers and research institutions that file for patents or IP rights for innovations arising from the use of genomic datasets should publicly disclose their intentions to do so and how the plan to ensure that any products developed from the innovation will be made accessible to study populations.

- Innovations from genomics research projects in Africa that are suitable for use in the African context and which addresses local health needs should be prioritised for translation.

- Funders and research institutions should develop a mechanism for tracking how the outcome of genomics studies are being used to improve healthcare for populations in Africa and if there is access to proven interventions by study population.

3.2 Solidarity

The principle of solidarity places prominence on the community over the individual. When study populations in Africa agree to provide samples and data for genomics studies, they do so more for communitarian-based solidarity reasons, especially as little or no immediate benefits may accrue to a study participants and/ or their communities (van Schalkwyk et al., 2012, Igbe and Adebamowo, 2012). By donating samples to biobank and participating in genomics research, research participants hope to contribute to the common good, that is improving human health through scientific and medical advancement (Igbe and Adebamowo, 2012). Empirical evidence shows that motivations to participate in genomics studies in Africa vary but are often associated with a desire to contribute towards finding solutions to the disease under study at the time as well as to know their individual health status (Masiye et al., 2017, Tindana et al., 2012, Moodley et al., 2014, Ogunrin et al., 2018). Therefore, it is important that genomics research in Africa: aligns to the health needs of populations in Africa and also ensure that study communities benefit from their participation in genomics research.

- In participating in genomics research, study populations hope that their samples and data would be used to advance science and medicine for the benefit of the world's population. However, to prevent a genomics divide between HICs and Africa, which may eventually widen global health inequities despite the participation of African populations in genomics research, genomics research in Africa should prioritise research on health conditions that are a major contributor to the disease burden in the study population. The same applies for future uses of samples and data from genomics research and biobanking projects in Africa. The idea is to promote with communal values, whereby one supports the other to allow for human flourishing.

- Biobanks and genetic databases have an obligation to share samples and data with other researchers in ways that allow for maximum use of samples and data.. Therefore, datasets from genomics research and biobanking projects in Africa should be made available for research on the health needs of African populations. The responsibility for this lies with a

broad range of stakeholders, including but not limited to: researchers, research participants, funders, journal editors, data access committees, research institutions and policy makers.

- Given the possibility that African researchers may not have adequate resources and capacity to use samples stored in biobanks and genomics datasets. Data access committees, biobanks and funders should prioritise research projects that involve African researchers and research institutions. This would ensure that African researchers are supported to use samples that were collected in primary projects and the data generated thereof to pursue research on the health needs of African populations.

- Participation in genomics research and biobanking projects provide little or no direct benefits to study populations. However it is premised on the promise that it will facilitate science and, in the long run, improve the health of populations in Africa. Also our conceptual analysis as well as empirical evidence (Masiye et al., 2017, Moodley et al., 2014, Ogunrin et al., 2018) suggests that motivations to participate in genomics research and biobanking studies are grounded in reciprocity-based solidarity as well as the desire to contribute to the advancement of science. Because genomic research is still at the developmental stages and it is unlikely that the benefits of such research will accrue to current biobank donors, genomics research and biobanking consortia in Africa establish appropriate benefit sharing agreements with study communities and LMIC researchers either at the project level or at the level of the consortium. This could for example be through continuously communicating research findings and progress to research participants and host communities, including information on the uses of samples and data. This also has the potential of building trust.

3.3 Mutual Trust

Trust is a person's reliance on someone or something to carry out their responsibilities or keep to their promises (Beauchamp and Childress, 2001). It is a necessary precondition of solidarity and it is difficult to imagine solidarity-based relationships that are void of trust. Trust is characterized by openness, reliability, accountability, dependability, and consistency (Bligh, 2017, Hardin, 2002, Michael et al., 2008). The success of any genomics research and biobanking project in Africa will depend not only on the quality of samples collected or the researchers and institutions involved, but to a large extent on building and maintaining the trust and support of all stakeholders (Carr and Littler, 2015, Bull et al., 2015). For example, there are broad perceptions that the expertise and contributions of African partners involved in international collaborations are not recognised and that HIC partners are seen as self-sufficient collaborators (Parker and Kingori, 2016). This is a call to recognise the interdependence of all stakeholders

within a research collaboration and an acknowledgement that each is making a significant contribution to the success of the project (Munung et al., 2017), without which there may be a breakdown of trust, leading to refusal to participate in studies or to share samples and data. This could have severe implications for the sustainability of genomics studies in Africa.

- Genomics research and biobanking consortia in Africa should develop data and sample sharing policies that recognises the contributions of African researchers, study populations and primary data producers. This may include: recognition in publications emanating from the use of data, access to patents and IP rights; and informing stakeholders of how samples and data have been shared and used for the advancement of science and healthcare. The lack of this could weaken partnership bonds and break trust between collaborators.

- African researchers should identify ways of engaging study communities on the purposes and outcome of their studies and the social and ethical implications. This shows respect for study communities and likely to build trust between researchers, research institutions and study communities. It would also empower study communities to effectively participate in deliberative decision-making on sample and data sharing in particular and genomics research and biobanking general.

- For reasons of trust and trustworthiness, research institutions involved in primary studies should serve as custodians for samples and data stored in biobanks and databases respectively. This will imply their involvement in making decisions on access to samples and data. Ideally a committee such as the data and biospecimen access committee (DBAC) could be asked to take on such a role. Such a committee should include all stakeholders who may be affected by decisions related to sample and data sharing, including: representative of participants, community representatives, REC members and researchers in LMICs.

- Research that demonstrate long-term research collaborations or plans for long term collaborations should be prioritised by DBACs when the make decisions on access to samples and data. Funders should also prioritise projects that demonstrate or has a plan for long term collaborations. Long term collaborations tend to build a system of trust that may incentivise data sharing. Also solidarity is stronger within inner circles. There are already observations that researchers in Africa are more likely to share data with researchers with whom they have an established and trusted research collaboration (Carr and Littler, 2015, Bull et al., 2015).

3.4 Reciprocity

Reciprocity refers to the symmetrical arrangement of giving and receiving, not in terms of giving back, in kind, what one has received, but in terms of the value of what has received. Whilst participants in biobanking and genomics research maybe aware that no direct benefits are likely to accrue to them as a result of their participation in genomics research and biobanking projects, yet they opt in to studies (altruism) for the benefit of mankind (Igbe and Adebamowo, 2012, Moodley et al., 2014, van Schalkwyk et al., 2012). However, a potential exchange (incidental reciprocity) may apply in cases where benefits arise in the future. In this case, reciprocity is reflected more as a communal value where research participants take responsibility for the health of others (*I am, therefore you are*), and their altruism should be matched by similar moves from institutions hosting biobanks.

- Genomics research and biobanking consortia should clearly articulate appropriate benefit sharing policies either at the project level or at the level of the consortium. This may include possibilities for: health development projects, capacity building, feedback of research results, public education in genomics and access to genomic medicine or interventions derived from population genomics studies in Africa.

- Genomics research and biobanking consortia should develop plans for ensuring sustainable access to proven interventions or products that may arise from genomics research projects in Africa or the use of samples and data from these projects.

- Genomics research and biobanking consortia in Africa should state: what kind of benefits are likely to accrue to study communities; who would have access to these benefits (individual participants, research groups, and study communities, public; and how they will be made available. At the minimum, key findings emanating from primary and secondary research studies should be communicated to study communities. African researchers/research institutions and secondary users of data and samples should identify possible mechanisms of communicating these findings to the study community.

- Reciprocity also requires acknowledging the contributions of the samples and data providers. Secondary users of samples and data should acknowledge the contributions of primary researchers who made samples and data available for research. Scientific journals, publishers and funders should identify ways of recognising the contribution of different African researchers who are involved in the generation of the primary data or collection of samples stored in biobanks. This may take several forms including but not limited to: collaboration, citations, acknowledgements and co-authorship.

Genomics has the potential to improve knowledge on human heredity and health. It is important that countries who contribute samples and data for this purpose are empowered to carry out research that is responsive to the health needs of their societies. For biobank donors, this may be through doing research that is responsive to the health needs of their communities. However, another stakeholder group whose interest needs to be considered are the African researchers. Given the limited research capacity in Africa, especially for high-through-put genomics studies, the efforts by African researchers should be matched by parallel activities to build their capabilities to use these samples and data to answer research questions of interest to them. Without which, fears of exploitation of African researchers in global health collaborations will persist, leading to an inertia for data and sample sharing. Therefore, it is recommended that:

- Funders and HIC partners of genomics research and biobanking projects in Africa, by virtue of mutual reciprocity, should support capacity building activities so as enable African researchers participate in, and contribute to, world class genomics research. This will also ensure that all partners are able to equitably contribute in scientific collaborations. Capacity building should take the form of individual and infrastructural capacity building and the fostering of long term research partnerships.

Reciprocity is also about mutual respect and exchange of information (Nzimakwe, 2014, Ramose, 1999). It requires that all stakeholders should be able to listen to the viewpoints of others, to acknowledge their contributions and to be willing to change their initial viewpoint following a reasoned argument.

- Genomics research and biobanking consortia must develop approaches and platforms that allow all stakeholders affected by a decision to make a contribution to policies and procedures on the access and use of samples and data.

3.5 Shared Responsibility

Shared responsibility is about assigning responsibilities to different stakeholders based on the roles that they normally perform. Shared responsibility adopts a cooperative approach that is based on the equitable sharing of responsibility amongst all stakeholders. This will imply that the more powerful stakeholder be assigned more responsibilities than the less powerful stakeholder. In table 4 below, we present the different stakeholder groups in genomics research and biobanking and possible roles and responsibilities. This is based on the functions such stakeholder groups assume in genomics research and biobanking consortia in Africa (functional requirement principle).

Table 4: Roles and responsibilities of stakeholders in genomics research and biobanking in Africa

Stakeholder	Description of stakeholder group	Roles and Responsibilities
African Researchers	Researchers based at institutions in Africa and who are directly involved in genomics and biobanking projects.	• Directly responsible for designing and implementing projects that addresses the health needs of African populations. • Contribute samples and clinical data to the biobank. • Generation of primary datasets. Data may include: clinical information, phenotypic genetic variation and microbiome sequence data. • Ensure that study populations benefit from their participation in genomics studies including access top proven interventions that may arise from the use of samples and data. • Identify what kind of patents may be acceptable for innovations that arise from genomics and biobanking projects in Africa.
Researchers in HICs	Researchers based at institutions in HICs and who are directly involved in genomics research projects in Africa.	• Involved in design of the study • Provide research support to partners in Africa.
Funders	Organisations in HICs and LMICs who fund genomics research projects.	• Provide financial support for project. • Allocate research resources based on the needs of stakeholders and towards health equity oriented goals (research capacity building, research that addresses the health needs of populations in Africa).

Governing body within the consortium	Should be made up of all stakeholders who are likely to be affected by decisions taken at the level of the governing body. It should at the very least include representatives of African researchers; study populations; funders. Representative of each stakeholder group should be proportionate and should capture the diversity within the stakeholder group (for example representative of African researchers at the level of data access committees should include both junior and senior researchers).	• Take major decisions on behalf of the consortium • Advise stakeholders on project related activities • Ensure that genomics research in Africa furthers the ideal of health justice
Data and bio specimen access committees (DBAC)	An independent advisory group responsible for making decisions on access to samples and data.	• Review request for access to data and samples. • Ensure that access to samples are provided to projects with clearly health equity oriented goals. • Prioritise projects that have plans for long term collaboration with African researchers.
Independent organisation	Should be made of experts in genomics research and biobanking but who are not part of the consortium.	• Peer review of the consortiums scientific program funders • Check that a consortium is achieving its equity oriented goals by for example doing monitoring and evaluation of the consortium in cases where accountability mechanism where peer accountability is not sufficient. • Provide project-related advice to the consortium

Policy Makers	Ministries of Health, Science and Technology in Africa. Regional and global organisations with health and health research mandates. For example WHO, NEPAD, African Union.	• Support the development of best practices for genomics and biobanking including benefit sharing mechanisms. • Identify genomics research priorities for Africa. • Fund genomics research. • Support research translation. • Support research capacity building. • Ensure sustainability of genomics research in Africa.
Data and sample users.	Consortium members: This includes project PIs, their co-investigators and student and staff members named on grant proposals. External users: Any other person, not directly involved in primary projects.	• Submit new data generated to the consortium's database. • Submit annual reports on how data and samples have been used. • Collaborate with and/or acknowledge African researchers who collected samples or generated the data of interest. • Ensure that their research is align with genomics research priorities of study community or to diseases that are common globally but for which there are specific research and development needs in LMICs.
Healthcare practitioners	Doctors, nurses, laboratory technicians, and genetic counsellors.	• Implementation of proven interventions. • Participate in research priority setting. • Support the implementation of genomics research.

Continent wide scientific societies	Professional bodies with interest in promoting genomics research in Africa. For example: African Society of Human Genetics and the African Academy of Sciences.	• Identify genomics research priorities for Africa. • Serve as an educational and organisational forum for African scientists. • Advice genomics research and biobanking consortia in Africa. • Support the development of policies for genomics research.
Project Coordinating Centres	Designated entity that provides administrative support to the consortium.	• Day to day management of projects. • Administrative oversight and support. • Monitor consortium's activities to ensure that they are achieving equity-related goals. This may include: monitoring capacity building activities; involvement of African researchers in projects that use data and samples from the consortium.
Research Participants	Diverse group of individuals who voluntary provide samples and/or data to research projects and/or biobanks.	• Initial "providers" of sample and data. • Participate in decision-making on use of samples and data
Study communities	Populations where research participants are recruited from. It may be patient groups.	• Initial "providers" of sample and data. • Participate in decision-making on use of samples and data.
Research Institutions	Universities, research organisations, and hospitals	• Provide infrastructural support for genomics and biobanking projects. • Develop public engagement activities to ensure that study

		communities are aware of use of their samples and data. • Identify what kind of patents may be acceptable for innovations that arise from genomics and biobanking projects in Africa and ensuring that African researchers are part of patents and IP applications where necessary.
Research ethics committees.	Committees made up of people of diverse disciplinary backgrounds who undertake the ethical review of research projects involving humans.	• Review and approve research studies with the aim of protecting research participants and ensuring that research is of social value to participants or study communities. • Oversee the safety, rights and welfare of research participants.
Journals	Intermediary between investigators who gather data and write research reports and readers of research results (healthcare professional, scientists and lay people).	• Publish outcomes of research to improve scientific knowledge, patient care, and health outcomes. • Ensure that articles published in journals acknowledge the contributions of researchers who generated the data e.g. acknowledgement of data providers, or citeable datasets.

In addition to the roles and responsibilities assigned to the various stakeholders, some stakeholders have additional moral obligations for promoting justice in genomics research and biobanking in Africa

- Researchers and research institutions in Africa have an obligation to design projects that address the health needs of study populations. In doing so, they should involve all stakeholders who may be affected by this. This may require doing stakeholder mapping to identify key stakeholders for the different projects. Particular efforts should be made in including African policy makers in decisions about research priorities for genomics research and biobanking.

- Funders should ensure that funding schemes for genomics research and biobanking in Africa are designed to further the ideals of health justice, that is: genomics research should be aligned to health needs of study populations, have defined plans for translation of research findings; and build research capacity in Africa. Also resources should be assigned to the different stakeholders based on their needs.

- Policy makers in Africa have an obligation to articulate their national research priorities and earmark those that genomics research is likely to make a significant contribution in improving the health of populations in Africa. Where they are unable to do so, international agencies such as the WHO could support them in this role. Where national health research priorities exist, funders should align calls for funding for genomics research with these priorities.

- Institution(s) or persons responsible for implementing benefit sharing should be identified by the consortium, and their roles and responsibilities clearly defined. The role of other stakeholders who may be involved in the process such as researchers, funders, commercial bodies and research institutions should also be spelled out.

3.6 Shared Sovereignty

Knowledge is like a baobab tree; no one person can embrace it with both arms

Governance is about the processes and interactions of stakeholders who share a common goal. It allows for members of a society to live together and to cooperate. In deciding who should be involved in decision-making, genomics research and biobanking consortia should identify key stakeholders (see section 3.5, “Shared responsibility”). All stakeholders who may be may be affected by the decision and the influence they have on the decision-making process. Given the power differences between stakeholders in genomics research and biobanking programs in Africa, it is essential that in setting up decision-making structures and processes, attention should be given to the power dynamics, for example which stakeholder group are likely to have more influence on decision-making. Shared decision-making is characterised by: inclusivity; relevance; deliberativeness; consensus decision-making and publicity.

3.6.1 Inclusivity

Genomics research and biobanking consortia should be cognisant that whilst deliberative processes consider stakeholders within an institution as political equals, societal norms and practices may influence the ability of some participants to effect decisions and outcomes. Also, the more powerful participant tends to dominate the decision-making process and this may skew the final decision in their favour (Rawls, 1993). Given the diversity of stakeholders involved in

genomics research and biobanking in Africa, all stakeholders whose basic interests are affected by decision should be included in decision-making processes, especially marginalised and vulnerable stakeholders. This has the advantage of enabling different stakeholders to refine their personal opinions and also ensures that research serves the interests of study communities (Pratt et al., 2016). Generally, processes that are designed to be deeply inclusive are more likely to produce decisions that reflect the needs and interests of society as a whole. Excluding any one group of stakeholder may weaken the legitimacy of governance mechanisms.

- In developing policies for genomics research and biobanking in Africa, genomics research and biobanking consortia should identify all stakeholders who may be affected by the policies and include them in the decision-making process. In doing so, they should into account: power differentials between stakeholders, how it may influence on decision-making and develop mechanisms to minimise one stakeholder group dominating the decision-making process.

- There is a need to capture the diverse voices within genomics research and biobanking projects in Africa. Each stakeholder affected by a decision should be given agency and should have an equal chance to voice their opinion. Particularly important is the need to include voices of disadvantaged groups and stakeholders who are more vulnerable to exploitation. In the case of genomics research and biobanking in Africa, this will include primary sample and data providers (African researchers, junior researchers and research participants). This could be achieved through a variety of means including: consultations, collaborations, focus group discussions and public engagement activities. By ensuring substantive representation (i.e. including the voices of all stakeholder groups), genomics research and biobanking projects will be allowing for power and influence to be distributed to stakeholder groups who often have a curtailed voice in research programs.

- In deciding who should be involved in a particular decision-making process, genomics research and biobanking consortia should categorise different stakeholders based on the influence they have in the decision-making process and on the final decision. This may ensure that decision-making is free from unequal power distortions between stakeholder's distortions. Stakeholders who have sufficient power to disrupt or influence a particular decision-making process should take on a consultative or advisory role and should therefore not be given voting rights as they already have sufficient bargaining power.

- To enable all stakeholders to make contributions to decision-making and policy, genomics research and biobanking consortia should identify factors that suppress people's opportunities to participate equally in decision-making (for example structural barriers, limited capacity and norms of discourse), and then develop mechanisms that will empower them, and optimise their participation in decision-making. This may include building their capacity in genomics and biobanking through research, public literacy and having appropriate resource allocation mechanisms.

- To minimise the potential of one stakeholder group having considerable influence in decision-making processes is important, it is important that the affected stakeholder groups are not only represented, but that that no one group is disproportionately represented compared to the others.

- Achieving inclusivity also requires going beyond stakeholder representation to include how and when they are involved. Genomics research and biobanking consortia in Africa should develop mechanisms of including sample donors and their communities in every phase or stage of the projects including: research agenda setting, design and secondary uses of data and samples, policy development etc. While there maybe conceptual challenges to achieving this in practice, they may be overcome through designing appropriate community and public engagement activities.

3.6.2 Relevance

The third requirement of shared sovereignty is that decision-making should appeal to the values of all stakeholder groups.

- Solidarity, reciprocity, shared sovereignty and trust are key principles in African settings and therefore to minimise the possibility of fears of exploitation, these principles should guide the development policies.

- The values and principles that would guide decision-making should be stated upfront by genomics research and biobanking consortia in Africa. These would ensure that these values and principles are promulgated when designing policies for genomics research and biobanking in Africa. Final decisions should reflect the values and principles of all stakeholders who may affected by the decision.

- Genomics research and biobanking consortia should develop accountability policies that involve communicating study communities about the progress and outcome of research projects in which they are involved.

3.6.3 Deliberativeness and consensus decision-making

The importance of reasoned deliberative dialogue lies in the fact that it creates an enabling environment to make decisions that are relevant for communities, and to resolve issues amicably (Fishkin, 2011, Pratt et al., 2016b, Valadez, 2018, Nyerere, 1968). Also, powerful partners always tend to present their views as norms but if less powerful stakeholders are given a voice, the deliberative process may reveal salient biases and may subsequently influence the more powerful partners to change or revise their positions (Young, 2001, Young, 2002). Given the diverse stakeholder groups that are involved in genomics research and biobanking in Africa and the power differences between them, efforts should be made to adopt a deliberative approach to decision-making that seeks to mitigate those power dynamics. Each stakeholder group should be given a chance to present their case and to give reasons for their positions.

- Decision-making within genomics research and biobanking governance structures (steering committees, data access committees etc.) should adopt a deliberative process. This applies to processes for making decisions such as research priorities, policy development and decisions on access to data and samples.

- Stakeholder groups who may be affected by a decision should be given a chance to present and give reasons for their own points of view; listen to the reasons of others and debate on issues in which they disagree or have conflicting ideas. By giving a chance for reasoned argument, the voices of the all stakeholders would have been considered by the different. At the end of the process, the different stakeholders may not necessarily agree on the final decision, but their perception of the problem may change. The idea is to be able to reach a conclusion that is acceptable or considered fair by all.

- Genomics research and biobanking projects in Africa should develop mechanisms for engaging and deliberating with the public on key issues around genomics and biobanking. This may be done through: consultancy, feedback or the use of participatory approaches to stakeholder engagement.

- Decision-making should be by consensus. The voices of all stakeholders who may be affected by the decision should be represented in policies and decision-making. There should also be

a substantive representation of the voices of all stakeholders. That is, physical representation of the stakeholders is not sufficient.

- There should be mechanisms in place to revise decisions that have been made especially in light of new evidence.

3.6.4 Publicity

Publicity and entails making final decisions and the reasons for them publicly available. This ensures that stakeholders understand the moral basis by which final decisions are based (Daniels and Sabin, 1998, Daniels and Sabin, 2008b). It also has the advantage of improving transparency (Daniels, 2000). Publicity, and by extension transparency, could be practically implemented through open meetings, circulation of minutes and the use of other open communication processes (Byskov et al., 2014).

- The reasons for final decisions should be made publicly available as this gives room for stakeholders who were not involved in the original process and who may want to appeal the decision to have an idea on the basis for which the decision was made.

- Minutes or reports of meetings should be made available to all stakeholders who may be affected by the decisions taken at meetings.

- Study populations should be informed of the outcome of decisions that will affect them and the reasons for such decisions. Appropriate means of communicating with these stakeholder groups should be identified and may include public engagement activities or other methods that were used for engaging research participants.

3.7 Shared Resources

Resource allocation is a major area of conflict in global health research and raises a range of ethical issues related to justice and fairness (Chi and Bump, 2018, Daniels, 2016). One key question relates to the equitable distribution research resources between LMIC and HIC partners (Pratt and Loff, 2011, Pratt and Loff, 2014, Benatar, 2001, de Vries et al., 2015b). Some of the ELSIs in genomics research and biobanking (e.g. exploitation of African researchers and study populations, ownerships of samples and data, IP rights and patents) are associated with the allocation of resources in global health research. SHG suggest that the distribution of resources should be such that a high proportion of the project resources are used to support the research of the LMIC partner (Pratt and Hyder, 2016, Pratt and Hyder, 2017).

- Genomics research and biobanking consortia in Africa should develop collaborative models that are equitable in nature and that ensure that a majority of the resources (funding, samples, data etc.) are controlled by African researchers and research institutions, unless doing will present a challenge to the overall conduct or implementation of the studyThis is because inequalities in resources tend to confer more benefit to the HIC partner and have tremendous impact on key research procedures and outcomes such as: ownership of data and samples, publication outputs; intellectual property rights, and access to the benefits of research.

- Data should be made more widely available to the research community as this may accelerate and enhance health research globally. However, given the history of exploitation and limited health research capacity in Africa, there is need to recognise that whilst open sharing is important, it may also have negative impact on African researchers, unless there are mechanisms in place to ensure that they have the capacity to analyse the data (sections 1.3.2a and 1.3.2e).

- Samples and data are a valuable resource in genomics research and biobanking. Priority for secondary use of samples and data should be given to research that: 1)addresses the health neds of population groups in Africa; 2)have a strategy that promotes uptake of research findings in ways that benefit study populations; and 3)has plans to develop the capacity for LMIC institutions and researchers. Decisions on what to prioritise for funding and for secondary use of data and samples should include, at the minimum, representatives from the following stakeholder group: funders, African researchers (both junior and senior to capture the views different levels of researchers), HIC researchers, research participants and policy makers in Africa.

- Authorship of research publications, patents and intellectual property are key resources and a major point of contention amongst genomics researchers. Research institutions and journals should identify ways of assigning authorship, IP rights such that they are equitably distributed. A way around this is to develop and implement fair and transparent practices on authorship, benefit sharing, intellectual property and ownership and to ensure that the policies recognise the contributions of data producers and sample providers.

3.8 Transparency

Transparency is a hallmark for good governance. Whilst it is a difficult concept to define, in global health, it has been likened to activities such as: open governance, free flow of information and civic participation (Gostin, 2008). This requires: that institutional and decision-making processes are open and comprehensible to all stakeholders; that there is the free flow of information amongst stakeholders; and that such information is accessible to all stakeholders. This recommendation is based on observations that there is limited transparency in global health programs, both at the level of decision-making and communication between the different actors. This often presents as a major challenge to global health efforts. Researchers in Africa have also called for transparency in decision-making processes within genomics research and biobanking consortia in Africa, arguing that it is key in fostering equitable global health research partnerships (Munung et al., 2017, Okeke, 2016). Open communication between research partners can also foster trust amongst stakeholders (Munung et al., 2017). It also shows that partners in a collaboration have nothing to hide from each other and are open to constructive criticism, which is a value that is critical in deliberative decision-making.

- Transparency in the governance of genomics databases and biobanks is critical for accountability purposes and for building and fostering trust between stakeholders. As a result, reasons for decisions on governance policies should be made publicly available. This makes it possible to hold decision makers accountable for the decisions that they make. Therefore, in the interest of transparency and public accountability, biobanks and databases ought to make publicly available, information about their activities and policies.

- Genomics research and biobanking consortia in Africa should develop mechanisms for reviewing requests for access to samples and data. The principles, procedures and policies for access to samples and data should be made publicly available. Such mechanisms should describe what samples and data can and cannot be used for.

- Genomics research and biobanking consortia should make public, information on how samples and data will be used and by whom. While it is difficult to clearly predict how data will be used, these projects should state this information upfront, to the best of current knowledge at the time. Once samples and data have been made available for use to requestors, the information about actual use should be made available.

- Transparency in decision-making processes is also vital. Consortia should make public the processes for which decisions on key ethical issues are made. For example, information

of how a consortium decides on who has custodianship of data and how IP rights and patents would be distributed in the case of an innovation. The ideal will be to make the decisions and the reasons for them publicly available.

3.9 Mutual Collective Accountability (MCA)

Accountability and transparency are hallmarks of fairness. MCA demands that stakeholders within a global health program should be answerable to one another and to other external bodies. Firstly, stakeholders must agree on a shared goal; have a common understanding of the goal; identify the important outcomes and indicators for measuring if they are achieving set goals; have standards of how resources will be used; and the how the plan to ensure meaningful participation of all stakeholder groups including in key decision-making processes that affect them (Ruger, 2012b). Genomics research and biobanking consortia in Africa should therefore establish ways for ensuring: that shared sovereignty is achieved; that resources are being used towards promoting health justice and that all actors are performing their roles and responsibilities. This could be done through setting standards for decision-making processes within the consortium; identifying indicators and benchmarks that may be used determine if these processes are inclusive and deliberative; and how resources have been allocated.

- Genomics research and biobanking consortia in Africa should state the specific responsibilities of the different stakeholders. This is because the responsibility for fair, efficient and equitable partnerships lies in a broad range of stakeholders including: researchers, research participants, funders, journal editors, data access committees, research institutions and policy makers. A list of stakeholders and their possible roles and responsibilities was presented in table 4; section 3.5.

- Given that the overall goal of population genomics studies in Africa is to use genomics as a tool to address global health inequities, Genomics research and biobanking consortia should clearly specific their equity oriented goals (see section 3.1) as well as detailed and realistic indicators of how the goals will be achieved. This would involve stating outcomes for equity related activities such as capacity building; research priority setting and research translation.

- Genomics research and biobanking collaborations should consistently monitor and evaluate the equity-oriented goals of the consortium. Monitoring and evaluation should provide a situation analysis of the consortium at the beginning of the project; document how the consortium is working towards achieving its goal of reducing global health inequities. These may include outputs related to: number of approved request for access

to data and samples; research that has been carried out using stored samples and data; number of research publication; authorship of papers by African authors, number of graduates; fellowships that have been offered; patents awarded; new interventions; policy impact; feedback of study findings to communities; and compliance with the agreement of secondary use of data and samples should be monitored. Outputs and metrics for evaluation should be elaborated by researchers, funders, study communities and policy makers.

- MCA also requires establishing ways for ensuring that shared sovereignty is achieved within a research consortium. That is, they should have standards for decision-making processes within the consortium as well as identify indicators of how to determine or evaluate if these processes are inclusive and deliberative.

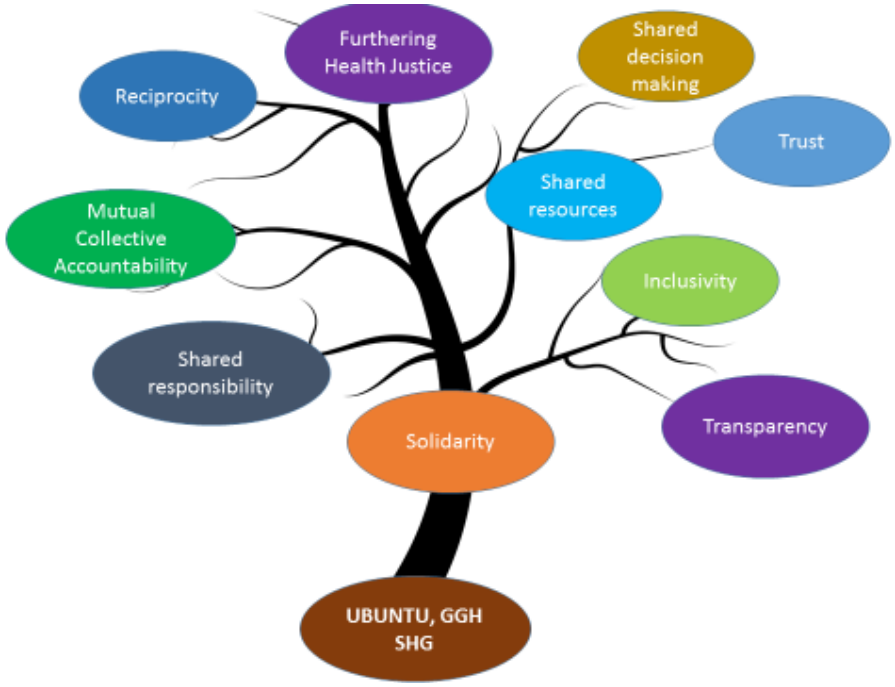
- MCA is also about engaging study populations, not just as key informants but also as agents of change that that have the potential to address concerns and issues that affect their community. There should be a mechanism to engage biobank donors and to address the concerns that may have related to the consortiums polices and processes.

- Given that accountability is not just about how stakeholders are carrying out the responsibilities assigned to them but also about engaging communities about the outcome and progress of research studies, genomics research and biobanking consortia should develop mechanisms of disseminating the outcome of research projects; informing stakeholders on how samples and data have been used; and how the activities are contributing towards achieving the consortium's goal of reducing global health inequities. This may require public engagement activities between host communities, research institutions and researchers. This accountability mechanism also has the potential to foster trust between researchers and study communities.

3.10 Chapter Summary

Governance is about the processes and interaction of stakeholders who share a common goal and who are involved in collective action to address a moral problem. In this chapter, we proposed a principles-based approach to governance of genomics research and biobanking in Africa. Principles-based governance focusses on the values of the organisation and how it may guide action. Based on the principles (Figure 4) identified in Chapter 2 through the conceptual analysis and the convergence approach, we proposed a principles-based governance framework for genomics research and biobanking in Africa.

Figure 4: Key principles that will support the governance of genomics research and biobanking in Africa



In the next chapters, I will use empirical methods to explore how these principles have been upheld in genomics research and biobanking in Africa. This will be through empirical analysis involving the reflective equilibrium approach involving: analysis of policy and governance documents for genomics and biobanking in Africa; and one-one in-depth interviews with different stakeholders in genomics research and biobanking in Africa.

Chapter 4: Methodology for Testing the Principles-Based Governance framework

The overall aim of our study was to propose a governance mechanism for genomics research and biobanking in Africa that will address structural inequalities and justice-related ELSIs in genomics research collaborations in Africa. In the previous chapter, I proposed a principles-based (conceptual) governance framework for genomics research and biobanking in Africa. This framework was developed using normative policy or practice oriented bioethics approach. This involved combining both normative and empirical. In this chapter, I will present the empirical methods that we used to test the principles and recommendations developed that informed our governance framework. This include a case study of H3Africa (section 1.2.2b) and data collection processes which consisted of 1) thematic analysis of H3Africa governance-related policies and 2) one-on-one, in-depth interviews with stakeholders in genomics research in Africa. The aim of the empirical study was to the framework against current governance practices of genomics research consortia in Africa, as well against the expectations of the different stakeholders, and to revise where necessary (reflective equilibrium) against the ethical intuitions of stakeholders in genomics research and biobanking in Africa, and to a lesser extent gain a practical understanding of how the principles are, or could be, implemented in everyday genomics research projects in Africa. The empirical arm of this work used the reflective equilibrium approach.

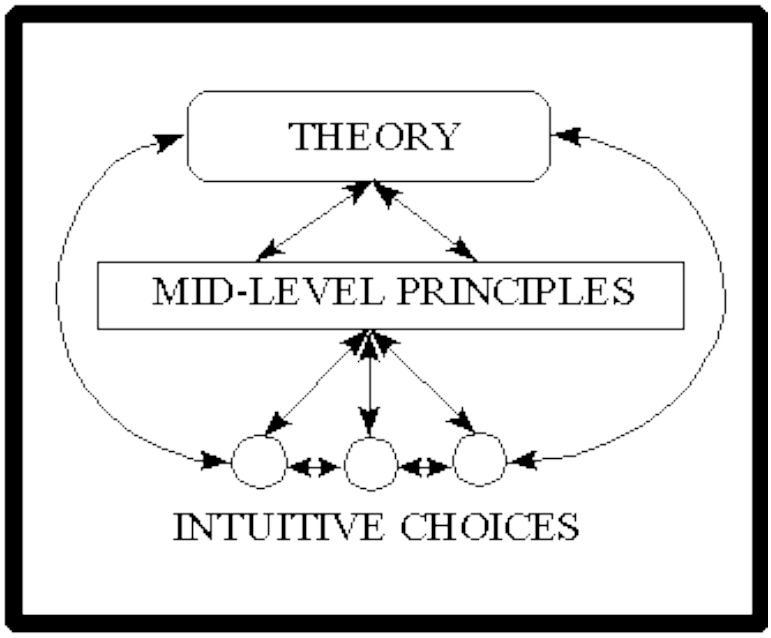
4.1 Empirical Methodology

Empirical bioethics (Ives et al., 2016, Musschenga, 2005) is becoming common practice in applied ethics owing to arguments that understanding people's moral beliefs, ethical intuitions, behaviour and reasoning in a specific area of practice can yield information that is meaningful for ethics (Borry et al., 2004, Davies et al., 2015). Empirical bioethics is in inter-disciplinary activity in which scientific methods of enquiry (qualitative and/or quantitative) are integrated into ethical analysis with the hope of reaching a conclusion that is not too abstract or far removed from realities (Davies et al., 2015). There are different approaches to empirical bioethics (Davies et al., 2015). Two prominent ones are normative policy or practice oriented bioethics (NPOB) and descriptive policy or practice oriented bioethics (DPOB) (Ives and Draper, 2009). NPOB is normative work on what policy or a practice ought to achieve and it involves combining philosophical bioethics to produce a rigorous and consistent analysis of an ethical problem and using empirical methods to gain a practical understanding of the ethical issue. DPOB, on the other hand is about using empirical method to gain an understanding of how bioethical reasoning

would take place in different context, what Ives and Draper, 2009, describes as the sociology of bioethics. We used the NPOB approach to achieve our study objectives. The conceptual analysis and the outcome of the process were presented in chapters 2 and 3 respectively.

The empirical part of this study used the reflective equilibrium approach. Reflective equilibrium principally consists in working back and forth between a theoretical considerations or principle that one believes in and revising it wherever necessary in order to achieve some degree of coherence (equilibrium) between the theoretical considerations.[13] The rationale behind reflective equilibrium is to "test" one's belief systems (values, principles etc.) against other beliefs or value systems that one may have, and constantly revising and refining these values or belief systems in cases challenges arise, with the overall goal of reaching an acceptable level coherence among the widest set of beliefs.

Figure 5: Diagrammatic representation of reflective equilibrium[14]



In this study, the idea was to check if the principles and recommendations in the proposed framework fit the actual circumstances surrounding genomics research in Africa and where possible/required, to tailor the recommendations to the actual circumstances of genomics

[13] https://plato.stanford.edu/entries/reflective-equilibrium/ accessed 08 October 2019

[14] https://www.bu.edu/wcp/Papers/TEth/TEthBulg.htm Accessed 08 October 2019.

research in Africa. The aim is to have a framework whose principles and recommendations can be considered binding for all rational agents and also not too abstract and far removed from reality (Davies et al., 2015). This is why I had started by developing a principles-based framework for genomics and biobanking in Africa (theory) and then used empirical methods to explore how the Framework aligns with the governance policies of genomics research consortia in Africa, as well as with the views and experiences of different stakeholders group. The empirical data was used to revise the theory as appropriate (reflective equilibrium). The empirical method that I used was the case study approach (Starman, 2013, Yin, 2003, Stake, 1995) and the case of interest to us is the H3Africa Consortium (section 1.2.2).

A number of methodologies have been used by researchers who seek to use empirical data to inform normative ethical work (Davies et al., 2015, De Vries and Van Leeuwen, 2010). These methodologies can be broadly categorised into dialogical and consultative (Davies et al., 2015). Dialogical approaches focus on the experiences of an identified group of people, not just as a source for reflection but also as part of the process of reflection and analysis (Widdershoven et al., 2009). It usually requires a combination of methods including: in-depth interviews and deliberative discussions. Consensus is central, but not a requirement for dialogical methodologies, and the conclusions of deliberations are taken as the findings of the investigation. Consultative approaches, on the other hand, involve using methods of scientific inquiry to test normative conclusions. In which case the participants or persons consulted where not involved in the normative theorising. Rather an external thinker (the researcher) developed the theory and then "consulted" with other stakeholders (Draper and Ives, 2007). Key to consultative approaches is going back and forth between the theory and the empirical data, and revising the theory until there is some level of coherence between the empirical data and the theory of interest (reflective equilibrium). The approach I used for this study was the consultative approach.

4.1.1 The Case Study Approach

A case study is a research design that offers a researcher an opportunity to probe, a phenomenon within its real-life context. It enables exploration of how and why a complex social phenomenon works and can bring out important contextual features. Case studies typically use a variety of qualitative research methods such as in-depth interviews, document analysis, and participant observations (Baxter and Jack, 2008, Patton, 1990, Yin, 2003). It enables the researcher to answer "how" and "why" type of questions while taking into consideration how the phenomenon is influenced by the case (Baxter and Jack, 2008). Different types of case study designs exist (Stake, 1995, Yin, 2003). In this study, I used the instrumental case study design (Stake, 1995). Instrumental case studies are research designs that help the researcher to refine a theory or a phenomenon of interest. The case is not the primary focus, rather it plays a supportive or

facilitative role in enabling the researcher to understand or refine the theory of interest. A benefit of the instrumental case studies is that there is a close collaboration, or at least there is some level of rapport between the researcher and research participants, thereby enabling research participants to freely express their views (Baxter and Jack, 2008). I am a student in the H3Africa consortium and once worked as a part time research assistant for H3Africa exploring issues of consent and regulation for genomics research in Africa. I was also involved, as a participant, in the development of the H3Africa "*ethics and governance framework for best practice in genomic research and biobanking in Africa".* I had therefore established some rapport with H3Africa activities and potential interviews.

4.1.2 The Case: H3Africa and the governance of justice-related ELSIs

A case is a bounded entity that is of interest to the researcher (Miles et al., 1994). In our study, the case is H3Africa governance policies and the phenomenon of interest to us is how H3Africa, as a genomics research and biobanking consortia in Africa, has upheld the principles recommended in our framework and what are the possible points of divergence. The aims and objectives of the H3Africa consortium have been described (Section 1.2.2). I will now present albeit briefly, H3Africa's governance structures and policy documents.

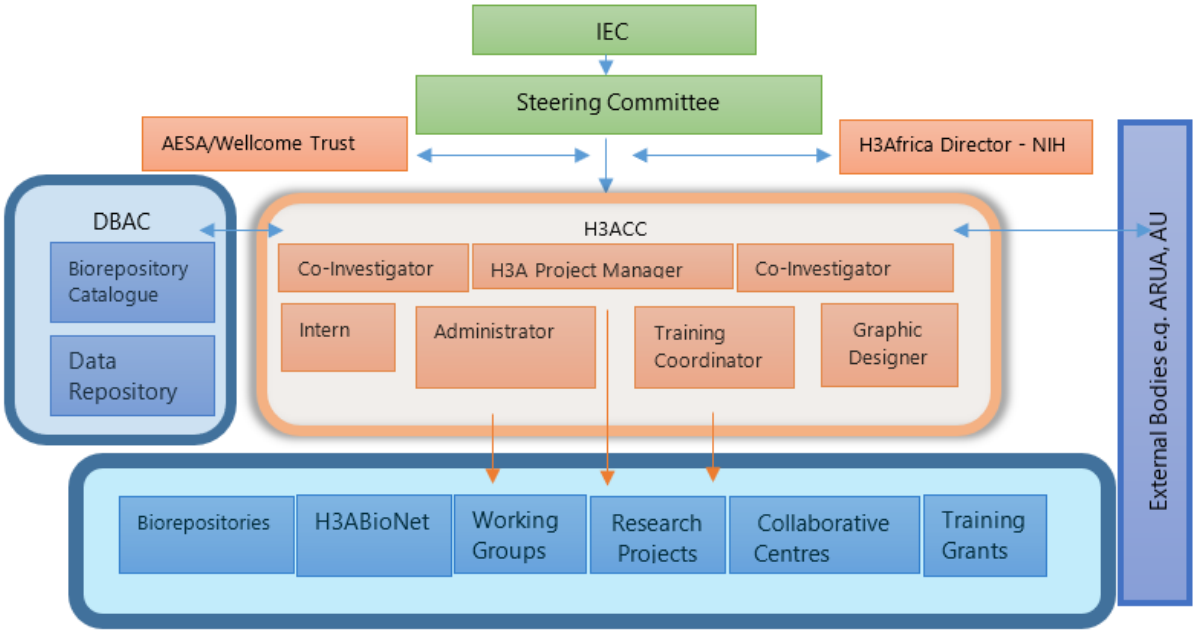
4.1.2a <u>Governance structures in H3Africa</u>

The main decision-making body of the H3Africa consortium is the steering committee (SC). The SC is made up of all principal investigators of H3Africa projects, and representatives of the two funders. All H3Africa principal investigators have a primary affiliation to a research institution in Africa. At the time of this study, there were 42 projects listed on the H3Africa website.[15] A number of these projects have been completed and others are new projects that received funding in 2018. Also, some researchers are principal investigators of more than one H3Africa project. Projects are nested in 14 African countries, with a majority being in South Africa.

While the steering committee is the major decision-making body, other key governance structures exist within the consortium including: an independent expert committee, working groups (WGs), the data and biospecimen access committee (DBAC) and the H3Africa coordinating center (H3ACC). These different structures report directly to the steering committee. Figure 6, shows the different governance structures within H3Africa and how they are managed.

[15] https://h3africa.org/consortium/projects (accessed 10 Oct.2018).

Figure 6: H3Africa Management Structure (Mulder et al 2018)[16]

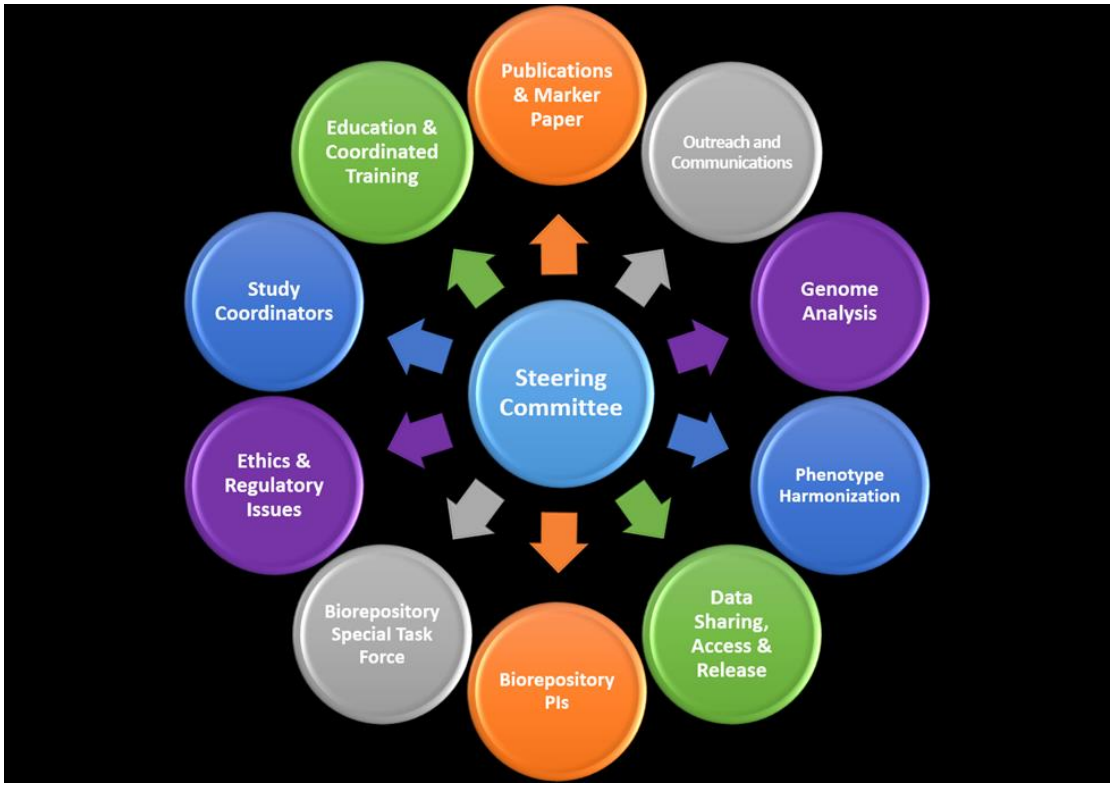


H3Africa has an independent expert committee (IEC) which is made up of international experts of different disciplinary backgrounds. Members of the IEC are not affiliated to any H3Africa project. Their role is to oversee the H3Africa consortium as a whole and to advise H3Africa funders. To do this, they meet quarterly and attend H3Africa meetings (biannual). Members of the IEC are appointed by the funders. Its current membership stands at ten, eight of whom are based in institutions in HICs, one in an African institution and one in an international agency.

In terms of the working groups (WGs), H3Africa currently has 12 WGs. These WGS (Figure 7) are organized around particular topics or areas of work and will generally have a defined deliverable that is in line with the consortium's activities. WGs are made up of researchers affiliated to an H3Africa project and nominated by their principal investigator to represent the project in the WG. Most WGs are led by chairs and co-chairs and meet regularly.

[16] https://www.slideshare.net/AfricanOpenSciencePl/h3africah3abionet-case-studynicola-mulder (Accessed 20 October 2018)

Figure 7: Working Groups in the H3Africa Consortium[17]



The activities of some H3Africa WGs have led to the development of policies or guidelines that are relevant for our study. For example, the ethics and regulatory issues WG has developed a number of ELSI guidelines for genomics research and biobanking in Africa The data and biospecimen WG has also developed best practices for sample and data sharing in H3Africa. Membership to WGs is not static and changes depending on availability of nominated members and project dynamics (active or completed projects).

The H3Africa Data and Biospecimen Access Committee (DBAC) is responsible for implementing H3Africa data and sample sharing policies. Members of the DBAC are appointed by the steering committee and are not (current) members of the H3Africa consortium. The DBAC is administered by the Alliance for the Acceleration of Excellence in Science in Africa (AESA), which also distributes some of the H3Africa funding (see Figure 6). AESA is an entity of the African Academy of Sciences. The DBAC can co-opt principal investigators, funders and the independent expert committee in when they need advice to make a decision on access to samples and data. However, these three stakeholder groups are considered ex-officio members.

[17] https://h3africa.org/consortium/working-groups Accessed 20 October 2018)

4.1.3 Data Collection and Analysis

In this study, I used qualitative research methods to test our principles-based governance framework against the governance policies of the H3Africa consortium as well as ethical intuitions of the different H3Africa stakeholders. The data collection phase was divided in three parts: 1) desktop analysis of H3Africa governance-related documents; 2) one-on-one, in-depth interviews with persons who have been involved in the development of H3Africa governance policies and; 3) observations, which were mainly a retrospective reflection of the process that led to the development of some H3Africa governance mechanisms.

4.1.3a Data Collection: H3Africa policy and governance–related documents

A consortium's policy documents and publications can provide rich information on its decision-making activities and the norms and principles that guide the governance of the consortium. We collected publicly available H3Africa governance related documents. This included: H3Africa policies; guidelines; and relevant publications by members of the H3Africa consortium. Table 5 shows the list of H3Africa publications that we included in this study. These documents were selected because they 1) specifically discussed or addressed issues pertaining to fairness and justice in genomics research and biobanking in Africa, and 2) because they were written or published by the H3Africa consortium or persons affiliated to it.

Table 5: H3Africa Governance-Related Documents

Document	Year	Code	Brief Description
Enabling the genomic revolution in Africa (H3Africa, 2014)	2014	H3Africa 2014	A journal article published in Science. It can be considered as a marker paper for the consortium. The article is authored by a number of H3Africa consortium members and provides information on the goals of H3Africa and anticipated activities of the consortium.
H3Africa guidelines for informed consent (2nd edition)	2014	IC Guidelines	A guide for developing informed consent for H3Africa projects. However, also recommended for use by non-H3Africa investigators planning to set up genomics research and biobanking projects in Africa.
Application for access to H3Africa data and biospecimen	NA	DBAC application	Application form to be used by researchers and other entities who plan to access and use samples stored in H3Africa biobanks and/or data generated from H3Africa projects.
Ethics and governance framework for best practice in genomic research and biobanking in Africa	2017	Best practice guidelines	The document list pertinent ethical principles and best ethical practices for genomic research and biobanking in Africa.
H3Africa data and biospecimen access committee guidelines	NA	DBAC guidelines	Provides information on the composition, working and procedures of the H3Africa data and biospecimen access committee (DBAC)
H3Africa biospecimen deposit material transfer agreement	NA	MTA	This form is used to record the transfer of biospecimen from H3Africa projects to an H3Africa biobank.
H3Africa data sharing, access and release policy	NA	DARP	This document lays out principles that the consortium considers important in striking an appropriate balance between ensuring that there are safeguards in place to protect biobank donors, while at the same time maximizing the ability of researchers to use samples and data stored in biobanks and databases

H3Africa data access agreement	NA	DAA	This document sets out the terms by which access to samples and data will be granted.
NIH-H3Africa request for application on ELSIs	2012	RFA-ELSI	Funding Opportunity Announcement for studies on ELSIs in human genomics research in African populations. It is complementary to funding announcements for H3Africa research projects and coordinating centres.
	2012	RFA-Research Projects	Funding Opportunity Announcement human genomics research in African populations. It is complementary to funding announcements for H3Africa research projects and coordinating centres
Harnessing genomic technologies towards improving health in Africa: opportunities and challenges	2011	White-Paper	A community-generated document outlining recommendations to the two H3Africa funders: Wellcome Trust and NIH. It is authored by members of two of H3Africa working groups: The WG on communicable diseases and the WG on non-communicable diseases.
Policy and guidance for managing conflicts of interest related to data and biospecimen access committee (DBAC) decisions	NA	DBAC	Document describes the processes for disclosing, identifying and managing conflicts of interest in the DBAC and to promote quality decision-making when conflicts of interest arise.
The H3Africa policy framework: negotiating fairness in genomics **(de Vries et al., 2015c)**	2015	De-Vries et al, 2015b	A peer-reviewed journal article authored by several H3Africa investigators and representatives of funders. The article discusses how fears of exploitation of African scientists prompted the development of policies for collaborative genomics research and biobanking in Africa.
Model framework for governance of genomic research and biobanking in Africa – a content description (Yakubu et al., 2018)	2018	Yakubu et al	A content description of the best practice guidelines for genomics research and biobanking in Africa.

4.1.3b Analysis of H3Africa governance documents

The predominant method of analysis was deductive thematic coding based on the principles and recommendations in the principles based governance framework (Chapter 3). The idea was to test the conceptual principles-based framework against the existing governance practices of a genomics research consortia in Africa. The aim was to explore how our proposed framework fits with current governance policies of genomics research consortia in Africa and where it is far removed from reality. The empirical data from the thematic analysis to revise the framework where necessary (reflective equilibrium). Despite doing deductive coding, there was minimal inductive coding in the case of new principles emerging from the document analysis. We then checked these new principles against our frameworks; principles to see if they were in any way related to the framework's principles or if they framework should be revised to include them as new principles.

To facilitate the process of analysis, all the documents were imported into the qualitative research software NVivo 12 (QSR International, 2018). To enable the inclusion of information on websites but which is not downloadable, I used NCapture (an extension file on Google Chrome that is supported by NVivo to get a pdf version of a website). I then thematically coded by NSM[18] using a pre-defined coding scheme (Appendix 4) which basically comprises of the principles from governance framework. The first few coding were checked with one of the supervisors for consistency and inconsistencies were resolved.

4.1.4 One-on-one In-depth interviews

The second part consist of one-on-one in-depth interviews with different H3Africa stakeholders.

4.1.4a Sampling

Purposive sampling was used to select research participants. Purposive sampling is a non-probability-based sampling strategy where particular settings, persons or activities are selected deliberately so as to obtain information that cannot be obtained in other ways (Devers and Frankel, 2000). This entails identifying and selecting research participants that are knowledgeable about the phenomenon of interest and who can give rich information about the subject matter (Creswell and Poth, 2016, Sargeant, 2012). In addition to having an informed perspective, research participants were also selected based on their availability and willingness to be interviewed (Bernard, 2017, Miles and Huberman, 1994). The advantage of this sampling strategy is that it provides the researcher with the opportunity to gain an in-depth understanding of the topic of interest (Patton, 1990).

[18] The student

4.1.4b Research Participants

Study participants were either persons who: 1) had participated in the development of governance policies 2) are involved in governance processes or; 3) had inside information on the functioning of the consortium, by virtue of their role within the consortium. Drawing on our knowledge of the processes of H3Africa policy and guidelines development, we made a list of persons fit into one of the three criteria mentioned above. These potential participants could be categorised into different stakeholder groups: African researchers, researchers from HICS, research ethics committee members, DBAC members, policy makers and funders (Table 4). Efforts were made to involve at least one person in each stakeholder group.

Emails were sent to potential research participants to invite them to be part of the study. The email had a description of the objectives of the project and why they were selected to be part of the study. Emails were sent to all identified persons (n= 28) as per the inclusion criteria stated above. A response was received from 19 persons, giving a response rate of 67.86%. Of these, three declined to be part of the study either because of time constraints, a conflict of interest or being unhappy with the study procedures. Of the 16 persons who accepted, 15 were interviewed. Repeated efforts to schedule an interview with one of the 16 persons failed. Table 6 gives a description of the 15 interviewees.

Table 6: Characteristics of Interviewees (n=15)

Group Characteristics	Profile of Interviewees	Number
Gender	Female	5
	Male	10
Stakeholder Group	REC	5
	Data access committee	2
	Policymakers	2
	African Researchers	4
	Funders	1
	Independent Expert Committee	1

While some of the interviewees fit into a particular stakeholder group, a number of them belonged to more than one stakeholder group. For example, there are researchers who are also policy makers or members of RECs. Members of the DBAC also belonged to different stakeholder groups. As a result, it was possible to have an interviewee who is an ethics committee member, a member of the DBAC and an African researcher. Therefore, during the interviews, it was common for some interviewees to draw on their experiences from the different roles they

occupy. However, for the purposes of this study, interviewees were classified based on their primary role within H3Africa. Questions were often directed towards that specific role.

4.1.5 One-on-one in-depth interviews

The one-on-one in-depth interviews were semi-structured (Mack et al., 2005). All questions were open ended (Annex 3: Interview guide). Open ended questions in qualitative research allows for the research participant to openly articulate their views in-depth and with little restrictions (Jacob and Furgerson, 2012, Kvale, 1996). It also allows for probing and/or follow-up questions (Denzin and Lincoln, 2005). The questions were related to the principles and requirements of our conceptual principles-based governance framework. The idea was to explore whether and how the framework's principles and recommendations were considered ideal by the different stakeholder groups and how they were promoted in H3Africa. Like in the document analysis we were searching for a level of coherence between practice and the theory of interest (reflective equilibrium). Before the interviews, I did an initial analysis of how the principles in our governance framework were upheld in H3Africa governance governance-related documents. I integrated some of the outcome from the document analysis into the topic guide. For example, sometimes interviewees were asked about a particular H3Africa policy and how that promotes fairness.

4.1.5a Pilot interviews

The interview guide was pilot-tested in December 2017 with a researcher who has been involved in the development of ethics frameworks for global health research, but who is not part of H3Africa. The main aim was to check for clarity of questions. Following the pilot, some questions were revised for clarity. These were mainly questions that where too theoretical in nature, including questions containing words like equity, reciprocity and solidarity. This was because some interviewees, based on their disciplinary background, were likely to struggle with questions containing these terms or may consider it too theoretical or philosophical. For example, in the pilot interview, the researcher had asked what reciprocity meant, though when the question was framed differently, his response indicated that he would expect some reciprocity-based actions.

4.1.5b Main Interviews

An interview guide was used for all the interviews. However not all questions on the guide where asked to every interviewee. As is normal with qualitative research, the interview guide was not rigidly followed (Patton, 1990, Dumay and Qu, 2011), rather it served as a pool where questions could be selected based on the stakeholder group, their discipline or their particular experience. For example, questions related to decisions on funding projects were not appropriate for REC members.

Interviews were conducted using different approaches: face-to-face meetings; Skype; telephone; and written interviews (Table 7). We used these different means because our interviewees were based in different countries around the world. All interviews were audio recorded. Before the start of each interview, informed consent was obtained from the interviewee. This included consent to audio record the interview. The purpose of recording was to ensure accurate transcription and to facilitate the process of data familiarisation. Interviews were conducted between December 2017 and November 2018.

Table 7: Approaches used for one-on-one interviews

Mode of Interview	Number of interviews
Face to face	03
Telephone	04
Skype	06
Written	02
Total	15

4.1.6 Observation

Observation forms a major part of qualitative research (Kawulich, 2005). In this study, I reflected, retrospectively, on the process that was used in developing an H3Africa governance and best practice framework (Yakubu et al., 2018). The development of the policy took place before the conception of this study. The process involved a number of virtual and physical meetings. Physical meetings took place in South Africa and Senegal. I was involved in the organisation of these meetings and sat through all the meetings. I had also followed the development of the guidelines up until when they were approved for use as a policy document for the consortium. This experience informed some of the interviews as well as analysis of the data though it didn't form part of the coding process. Also, one of my supervisors is a previous chair of the H3Africa ethics and regulatory issues WG. Discussions with this supervisor also helped add context during data analysis and interpretation.

4.2 Data Analysis

The first stage of data analysis began with the transcription of interviews. This was done *verbatim* from the audio recordings. To ensure accuracy , each transcript was reviewed at least once , to identify any errors or missing text. Where the recording was inaudible, "…" was used to signify that there was no sound or missing information. In addition to reading printed copies of the transcripts, I also listened to all the recordings at least twice. The purpose was to familiarise myself with the dataset (Charmaz, 2006, Creswell and Poth, 2016, Patton, 1990).

4.2.1 Coding

The data analysis was similar to that used for the thematic analysis of H3Africa governance-related documents. Firstly, all transcripts were imported into the qualitative research software NVivo 12 (QSR International, 2018). Deductive thematic coding (Vaismoradi et al., 2013) was used to analyse the transcripts, as codes were already pre-determined (principles that informed the framework). Deductive coding is a method of qualitative data analysis that uses a predetermined framework to analyse the data (interview transcripts, field notes, pictures). It is therefore a theory-driven approach, whereby themes or codes selected are predetermined by an existing theory, in our case, the principles in our governance Framework. Minimal Inductive coding was done for interview transcripts, mainly where the interviewee was articulating a point related to governance which did not form part of the Framework's principles.

Like in the document analysis, I did the first round of coding. The coding was checked with one of my supervisors and discrepancies were resolved. Following that, I coded the rest of the transcripts. Because deductive coding was principally used in this study, the codes (principles of the framework) had been jointly agreed upon with my supervisors during the development of the governance framework and the analysis of H3Afrca governance documents. Therefore, only differences in the actual coding were discussed and resolved and not the codes themselves. In cases of new codes (inductive coding), the content of the codes were discussed with supervisors to see if the constitute a new principle or if they inform one or more of the principles in the Framework.

4.3 Ethical Considerations

Research ethics clearance was obtained from the University of Cape Town, Faculty of Health Science Research Ethics Committee, HREC REF: 548/2016 (Annex 1).

Before the interviews, informed consent (Annex 2) was obtained from all participants. Consent documentation was sent by email to potential participants in the study invitation email. The aim of sending information sheet to research participants prior to the interviews was so that they could make an informed decision of whether or not they would like to be part of the study. Before the interviews, I also re-iterated the content of the information sheet and confirmed their willingness to be part of the study. Permission to audio record was also obtained from all participants. Audio recordings and informed consent forms were available only to the student and the supervisors. Once the interviews were transcribed, the transcripts were anonymised and all sources of identification replaced with codes and pseudonyms. This was to ensure that confidentiality was maintained at the highest possible standard.

In reporting the results of the in-depth interviews, names of interviewees have been replaced with pseudonyms to limit the chances of identification of study participants. Also, in some cases, slight edits were made to the quotes, mainly to remove repetitive words/phrases or exclamations. The purpose was to improve readability. No new words were added.

4.4 Limitations of the empirical study

The empirical part of this study aimed at testing our principles-based framework against governance-related documents of the H3Africa consortium, as well as the governance expectations and views of different stakeholders in genomics research and biobanking in Africa. Though a list of stakeholders had been identified in our governance framework, it was not easy to get a fine balance of all stakeholder groups. For instance, whilst we strived to interview people across different genders, age groups and levels of professional seniority, our interviews ended up being skewed towards senior males in academia. I acknowledge that greater diversity could have further enriched the study. However, I endeavoured to reach out to the different stakeholder groups and also to persons across the different management structures of the consortium but did not get any response from some potential participants. Also many of the consortium members who had participated in policy development or involved in governance structures are professionally senior and some stakeholder groups had not been involved in the development of policies.

Also, it was difficult in a single interview to explore in depth on all aspects of the framework, given that most the framework principles are quite multi-layered. For example, a governance requirement such as inclusiveness is broad and involves a range of requirements such that it will require a full study, to fully explore, what it really means for genomics and biobanking in Africa. This work will benefit from future studies that specifically seek to explore, in depth, separate elements of the framework.

This study would have benefited from a review of minutes of some H3Africa governance structures, for example minutes of steering committee meetings, or working group meetings where policy decisions were made or discussed. Attempts to get the minutes were unsuccessful. We did not want to use our insider access to obtain these documents, but we were also unable to receive copies of the minutes through formal channels.

4.5 Chapter Summary

In this chapter, I discussed the empirical methods that were used to test our proposed governance framework against the current governance practices of a genomics research and biobanking consortia in Africa, as well as against the ethical intuitions of different H3Africa

stakeholder groups. This involved the use of empirical bioethics approaches and qualitative research methods (document analysis and one-on-one in-depth interviews). The aim was to achieve some coherence between the principles-based framework and practical realities. In the next two chapters, I present the findings of the empirical study.

Chapter 5: Assessing Existing Governance Practices of a Genomics Research and Biobanking Consortia: The Case of the H3Africa Consortium

In Chapter 3, I proposed a principles-based governance framework for genomics research and biobanking in Africa. This was based on a conceptual analysis of: two accounts of global health justice and governance (SHG and GGH); and the African moral theory of *Ubuntu*. To investigate how the principles and recommendations proposed in the governance framework compare to the existing governance approaches of a genomics research and biobanking consortia in Africa, I used empirical bioethics approaches (normative policy or practice oriented bioethics, consultative approaches and reflective equilibrium). This involved qualitative research methods (Case study, thematic analysis of H3Africa governance-related documents and one-on-one in-depth interviews with stakeholders in genomics research and biobanking in Africa.

In this chapter, I present the results of the thematic analysis of H3Africa governance documents and how the upheld, aligned or diverged from the principles promoted in our governance framework. In presenting the results, I will provide a brief context to each principle, then state what was obtained in the data and end with an analysis and/or interpretation of the data and whether or not the policies align or diverged from the principles promoted in our governance framework. The results of the analysis are presented according to the nine principles promoted in the governance framework (Chapter 3). This includes: shared sovereignty, furthering the ideals of health justice (FIHJ), solidarity, reciprocity, transparency, shared resources, shared responsibility, mutual trust and mutual collective accountability.

5.1 Shared sovereignty or shared decision-making

Shared sovereignty (shared decision-making) is about democratic governance. It allows stakeholders to express agency and to ensure that their needs and perspectives are captured in decision-making. The advantage of shared sovereignty is that if properly done, it could address concerns of inequality in decision-making. Key indicators of shared sovereignty include: deliberativeness; inclusiveness; consensus; relevance; appeal and revision; publicity and conflict management. Voting may be used in deliberative decision-making, but attention must be on the quality of the decision-making process, ensuring that it is not elitist and that it captures the voices of all who may be affected by it (Pratt et al., 2016b, Young, 2002). In the review of H3Africa governance documents, I checked for these different indicators.

5.1.1 Decision-making structures within H3Africa

Two major decision-making structures emerged from the documents that were reviewed: The steering committee (SC); and the data and biospecimen access committee (DBAC). The SC is the main decision-making body (See Figure 6). While the DBAC is charged with making decisions on access to samples and data from H3Africa projects. However, a number of working groups (WGs) exist within the consortium, each tasked with a different activity but expected to report directly to the steering committee.

The SC comprises of African researchers and funders, mainly: Principal investigators of H3Africa projects and two representatives of the funders. However, *"additional funding members may join the meetings but do not have voting rights"* (de Vries et al., 2015c). These additional funding members are program scientists[19]. Program scientists are employees of the funders and are responsible for administering grant portfolios and working with principal investigators to negotiate the goals of their projects.[20] These program scientists take part in SC meetings and in the deliberations but do not have voting rights.

The DBAC is the second major decision-making body in H3Africa. It is an independent committee made primarily of non-H3Africa members. The DBAC is tasked with the responsibility to "*review and approve or reject all requests from the research community…..for access to datasets and/or biospecimens*" (DBAC guidelines). Members of the DBAC are appointed by the steering committee and it is said that the *"steering committee will consult more broadly to identify appropriate members of the DBAC"* (DBAC Guidelines). However, it is not stated who, or which stakeholder group, would be consulted. The majority of DBAC members are based in institutions in Africa. Its current voting membership stands at nine. Details of its composition is shown in Figure 8. Of the four scientists who are part of the committee, one is from a HIC but with research experience in Africa. The DBAC also has four ex-officio members: a member of the independent expert committee (IEC); a representative of each of H3Africa's major funders; and an H3Africa principal investigator. The size of the ex-officio members is almost half that of the voting members. The criteria for selecting members of the DBAC are not stated in any of the consortium's documents.

[19] In some documents (e.g. RFA ELSI and RFA research) Program scientists are also referred to as program officers or project scientists.

[20] https://www.niaid.nih.gov/research/program-officers

Figure 8: Composition of the H3Africa Data and Biospecimen Access Committee (DBAC)[21]

- *Ex officio* One PI
- *Ex officio* One Independent Expert Committee member
- *Ex officio* One representative from each of the major funders

Area of expertise	Number of Individuals
Scientist – relevant research	2
Biobanking expert	1
Data expert	1
Ethics expertise (genomic studies in Africa)	2
Legal expertise	1
Patient advocate	1
Demographer/Epidemiologist	1
Total	9 members

A third decision-making structure is the working groups (RFA-Research projects). As stated in chapter 4 (figure 7) there are currently 12 working groups (WGs) in H3Africa. The WGs may be considered decision-making structures, though indirectly. This is because some WGs are have in the past led the development of governance policies for the consortium. However policies developed by the WGs would have to be endorsed by the steering committee. WGs are ideally made of representatives from the different H3Africa projects and representatives are appointed by an H3Africa principal investigator. However, from our personal experience, membership in WGs is quite fluid, with some WGs having representatives of funders (program scientists).

After identifying the major decision-making bodies, we checked core H3Africa governance documents (Chapter 4; Table 5) to investigate whether the key indicators of shared sovereignty (deliberativeness, relevance inclusivity, consensus, publicity and appeal and revision) were reflected in H3Africa's decision-making structures.

5.1.2 Inclusivity

One way to promote equity in decision-making is through ensuring that decision-making processes are deeply inclusive of the different stakeholder groups, especially marginalised or

[21] https://h3africa.org/wp-content/uploads/2018/05/App-D-H3Africa-Data-and-Biospecimen-Access-Committee-Guidelines-final-10-July-2017.pdf Accessed 08 October 2019

disadvantaged groups and that no one group is disproportionally represented. There are three components of inclusivity are: breadth, qualitative equality and non-elite participation (Pratt et al., 2016b, Ruger, 2011).

5.1.2a Breadth of Stakeholders

Breadth is about the range and mass of stakeholders that are involved in decision-making. It should be such that each affected stakeholder group is proportionally represented so as to capture the diversity of perspectives within the research program.

Stakeholders that are typically involved in decision-making in H3Africa, as per the documents reviewed include: researchers (African and HICs), funders, community representatives, independent experts and program scientists. Compared to the other H3Africa decision-making structures, the DBAC is the most inclusive in terms of breadth. It is composed of African researchers (in the majority), HIC researchers, a representative of independent expert committee (IEC), funders and a community representative. It equally has a wider representation in terms of scientific discipline. The DBAC is also the only decision-making structure that has a representative a community representative (patient advocate). The steering committee, on the other hand, is made up of African researchers, members of the IECs and the funders. No other stakeholder group is represented in the steering committee. WG are predominantly made of researchers and funders (program scientists).

Decision-making in H3Africa is dominated by three stakeholder groups: funders, HIC researchers and African researchers, as these stakeholder groups dominate the steering committee and the DBAC. Whilst community representatives form part of the DBAC, their participation in decision-making is limited to reviewing request for access to data and samples.

5.1.2b Qualitative equality

To achieve inclusivity, all stakeholders affected by a decision should have an equal chance to influence the final decision-. Although the range and mass requirement are largely not met within the SC, there are measures in place to ensure that decision-making is not dominated by historically powerful stakeholders such as funders and HIC researchers. For example, in the SC, the greater number of African researchers *vis-à-vis* HIC researchers and funders could be understood to have the effect of promoting the voices of African researchers, thereby minimising the possibility of exploitation of African researchers. Also, some representatives of the funders on the SC do not have voting rights and may therefore be taking on a supportive role. This is in line with the qualitative equality requirement of shared sovereignty, which recommends that HIC partners play a rather supportive role in decision-making, allowing a greater number of representatives from LMIC institutions to be included relative to HIC partners (Pratt and Hyder,

2017). The same can be said of the DBAC which is made of 14 members, 9 of which have voting rights, whilst four are non-voting. The four non-voting members include: an H3Africa principal investigator, 2 representatives of the funders and a representative of the IEC (see figure 8). However, the number of community representatives or patient advocates compared to the expert groups and other stakeholders is relatively small and this may influence their ability to influence decision-making.

Qualitative equality is also about including the voices of each stakeholder group represented (substantive representation) in decision-making. That is, there must be some level of qualitative equality whereby all individuals have a fair opportunity to voice their opinion and to influence the decision-making process. It was difficult to determine from the document analysis, how this was promoted within H3Africa besides the dominance of African researchers in key decision-making structures. However, in a recent study, a genomics researcher in Africa called for *"regulatory procedures that will make sure that the African scientists are involved and are central to any decision involving the use of the samples and are actually involved in the publications and the intellectual property that emanates from such processes. African scientists should be at the centre of all of this. So it is not disadvantaging anyone"* (Munung et al., 2017). This may suggest that at the time of the study (2015-2016), there were perceptions that African researchers did not have an equal chance to influence decision-making compared to stakeholders from HICs. This is despite some of them being principal investigators..

Also, in developing some H3Africa policies, the ethics and regulatory issues WG adopted a consultative process, especially when engaging stakeholders who were non H3Africa members (de Vries et al., 2015a, Ramsay et al., 2014, Yakubu et al., 2018). My observation of some of the WG processes is that decision making followed a deliberative process. However, it will be important to interrogate how the different stakeholders who participated at these meetings feel about the engagement and deliberative processes that were adopted by some WGs, and if they found their voice in the overall process and in the final decision. It will also be important to explore how the qualitative equality component plays out at the level of the steering committee and the DBAC, given that though these structures are dominated by African researchers, a substantial number of representatives of the funders (including project scientists) and members of the IEC take part in deliberations. Overall, substantive representation was more visible within the WGs than at the broader level of the consortium.

5.1.2c <u>Non-elite participation</u>

Equally important in shared sovereignty is the participation of "non-elite" groups in decision-making. Besides the representation of African researchers, who can be considered historically disadvantaged within global health research programs, only the DBAC involves another

historically disadvantaged group, representatives of study communities (Best practice guidelines and DBAC guidelines). The DBAC has non-science experts such as fraternity and legal persons (see Figure 8). However, whether these non-expert members have an opportunity to impact on decision-making (substantive equality) is unclear, given their relatively small number compared to the expert group. For example, having single individuals representing study communities may not always be ideal especially when the rest of the DBAC is made up of experts. It may be worth having an additional patient group representative as part of the DBAC. This may limit the chances of supressing the voice of this stakeholder group.

5.1.3 Relevance

The second key requirement for shared decision-making, after inclusivity, is the relevance principle. The relevance condition demands that decision-making processes, and final decisions should appeal to the values and principles of stakeholders who may be affected by the decision.

The H3Africa best practice guidelines speaks to the relevance principle, stating clearly that the document is "*inspired by communal or solidarity-based worldviews that are important in many African countries. Such worldviews recognize that individuals are shaped by their relations to people around them, and emphasize respectful and harmonious relationships between individuals. It places central importance on reciprocity, consultation and accountability as key ethical values*". This suggest that principles such as solidarity and reciprocity and respect which are important in African communities and other parts of the world, were taken into consideration when developing this particular H3Africa policy. The guideline further mentions, with reference to informed consent and community engagement practices, that there is need for an African approach to decision-making stating that "*In many African contexts, individuals often take decisions in consultation with family, friends and community members. Frequently, there are also clear authority structures that must be respected in the engagement process such as permission from village chiefs and elders. In genomic research and biobanking, community engagement offers an important opportunity to build respect and trust between research teams and the respective communities*". Here the document again highlights respect, as well as trust as important principles and/values that are necessary when implementing genomics studies in Africa. The quotes above therefore shows that some of the principles promoted in our governance framework (solidarity, reciprocity, trust, accountability) are also considered important by the H3Africa consortium. A principle not in our framework but which is considered by the consortium to be important is respect. However, there is little detail in the documents reviewed about what the principle of respect entails.

5.1.4 Deliberativeness

Deliberativeness is the third requirement of shared sovereignty. Deliberative democracy demands that all stakeholders who may be affected by a decision should be given the opportunity

to propose solutions to the shared problem, give reasons for their position and be open to criticism (Young, 2002). None of the documents that were reviewed suggested if this was an approach to decision-making, although consultation was used in some cases. However, from our experience, the WGs (made primarily of one or two stakeholder groups), used deliberative processes when developing policies (personal observation). Usually, when developing a policy, the ethics and regulatory issue WG would first deliberate about certain policies at the level of WG meetings and would come up with draft policies that they consider to be fair and just. Once these policies have been identified, other stakeholder groups (mainly RECs and other African researchers) were consulted to discuss the proposed policies. In most cases therefore, persons invited to meetings to discuss guidelines where presented with draft policies for discussion.

5.1.5 Consensus decision-making

Following deliberative discussions, shared sovereignty demands that the final decision should be reached by consensus. Consensus decision-making is a form of group decision-making process whereby group members agree to support a particular resolution in the best interest of a group. For a consensus driven process to be considered fair, it must be: inclusive, deliberative and agreement seeking.

From the document review, voting is the main form of reaching final decisions in H3Africa, both at the level of the DBAC and steering committee. In the steering committee, each funded project and funding agency is entitled to one vote. At the level of the DBAC, final decisions will also be reached by voting (DBAC guidelines). It is also stated that decisions may be reached without discussions at a DBAC meeting but that in cases where the vote is not unanimous, the chair will make the final decision. It is not stated if voting is preceded by deliberations, however there has been some minimal use of structured group interactions and consensus-driven dialogue (de Vries et al., 2015a, Ramsay et al., 2014, Yakubu et al., 2018). Voting can form part of consensus decision-making. However, it must be preceded by deliberative discussions with the intention of reaching group agreement. This therefore aligns with our framework principle of shared sovereignty and the requirement for consensus-based decision making. However, further work is needed to establish whether voting was and/or preceded by deliberation.

5.1.6 Appeals and revision

The appeals and revision condition of shared sovereignty states that there should be mechanisms in place to appeal decisions and to revise the decisions in line with new evidence. The DBAC fulfils this requirement by making provisions for researchers to appeal a decision to reject their request to access samples and data. In the DBAC guidelines, it is stated that *"If a requester wishes to contest the H3Africa DBAC decision…….the requester may contact the H3Africa DBAC chair to discuss the issues or resubmit her/his request. The H3Africa DBAC Chair may approach the*

H3Africa steering committee for their advice in problematic cases". Besides this, there is no information on processes for appeal and revision, for example are requestors required to provide a detailed reasons for why their applications will be considered, will they appeal be discussed at a DBAC meeting or does the chair have the sole decision-making right, what kind of decisions can be appealed and how long is the appeal process? There is no mention of a process to appeal and revise decisions that are made by the steering committee.

5.1.6a <u>Conflict management</u>

The sixth requirement for shared sovereignty is that global health research consortia should have mechanisms in place to address conflicts.. Two major ways of managing conflict are discussed in H3Africa governance documents: mediation and the use of independent committees. Both are linked to the functioning of the DBAC and to the sharing of research resources (samples and data). The DBAC is an independent committee, therefore, no H3Africa researcher is part of the DBAC. The idea for an independent DBAC stems from arguments that despite the advantages of having primary researchers populate DBACs as they potentially have greater knowledge of the wishes of sample donors, they often want to exercise ownership and control over their data (Fecher et al., 2015, Kaye et al., 2009), rather than allowing maximum use of samples and data for the advancement of research. The approach by H3Africa for an independent DBAC therefore seems appropriate in addressing that level of conflict.

The H3Africa defines a conflict of interest as any situation whereby the personal interest or loyalties of a DBAC member may influence or affect the decision of the committee. The DBAC requires that members communicate with the H3Africa coordinating centre, or the Africa Alliance for Accelerating Excellence in Science in Africa (AESA), in advance, of any conflict of interest they may have for an application under review. AESA is an initiative of the African academy of Sciences and has an H3Africa portfolio which manages Wellcome Trust funded H3Africa projects. The DBAC member with a conflict of interest will then have to recuse themselves from discussion and voting on all applications for which they had indicated a conflict of interest.

Conflicts are also predicted to arise in cases where data and samples are used in ways that do not conform to the data access agreement (DAA) and in assigning intellectual property rights (H3Africa MTA). It is expected that this will be solved via mediation or adjudication by an ad-hoc committee made of approximately seven members and with a balanced representation of the: steering committee; funders; the provider or host biorepository; and the local research ethics committee. There are no indicators of what the mediation process will take into consideration.

5.1.7 Publicity

The last of the shared sovereignty requirement is publicity. The recommendation is that global health research projects should make publicly available, information on decisions that affect stakeholders; and the procedures by which the decision was reached. This allows all stakeholders to easily interrogate decisions made by the consortium, should the wish to do so. In H3Africa, reference to the publicity requirement is only made in relation to access to samples and data. The DBAC guidelines state that the H3Africa coordinating centre will publish (on the H3Africa website), a list of projects that have been granted access to samples and data samples. This, however, is in contrast to the data access release policy (DARP) which states that "*the coordinating centre will keep records of who gained access, and when, to ensure that the terms of access and the conditions of the publication embargo are complied with. These records will not be made publicly available, but will be available to the H3Africa steering committee for oversight purposes*". The quote above shows that information on access to samples and data will not be made available, thereby contrasting the DBAC guidelines. The DBAC guidelines (but not the DARB) align with our framework requirement for shared sovereignty that decisions, and the reasons for them, should be made available to all affected stakeholders.

5.2 Solidarity

The second principle promoted in our framework, after shared sovereignty is solidarity. Solidarity is a key principle in African communitarianism. It is about unity, based on shared values, objectives and standards (Wiredu, 2000). It supports an approach whereby members of a community work towards achieving a common goal even when they may have different personal values and opinions (Msila, 2015). The principle of solidarity overlaps with the principles of reciprocity and trust.

Solidarity is represented in H3Africa governance documents in two major ways. Firstly, there is the solidarity of HICs with populations in Africa. This is motivated by fears of a potential genomics divide which may worsen global health inequities (H3Africa White-Paper). The goal of H3Africa is to prevent this genomic divide thereby contribute to reducing global health inequities (H3Africa Consortium, 2014) . It is hoped that this could be achieved through the participation of African populations in genomic variation studies as well as through equipping African researchers with the tools and skills needed to carry out population genomics studies. This has led some funding agencies (US-NIH and the Wellcome Trust) in HICs to invest in population genomics research and biobanking in Africa, with the goal of preventing a genomics divide. The second is a call for solidarity from African populations to the global community. This is framed in line with the idea that understanding Africa's rich genetic diversity offers significant insights into a range of diseases as well as treatment strategies that could benefit populations not only in Africa,

worldwide (White-Paper, H3Africa, 2014). Population genomics studies on African populations could be facilitated through collaborative research and the sharing of samples, data and expertise between researchers. However, entrenched systemic and structural inequalities in health, research capacity and resources between HICs and Africa and a history of extractive research practices in global health programs in Africa, also requires that parallel attention be given to social justice and fears of exploitation of African populations and researchers in global health research. To this effect, H3Africa developed a number of policies for access to data and samples from H3Africa projects. Some of these policies include: the data access release policy (DARP) and the DBAC guidelines. These policies all support the sharing of samples and data (through the European genomics archive) with researcher from around the world, but with access being controlled by the H3Africa DBAC. However, priority for access would be given to researchers in Africa, especially those who were involved in the initial studies (DARP). The idea is to ensure that African researchers have more control of data and samples, thereby addressing concerns of exploitation of African researchers. This shows the adoption of solidarity based values by the H3Africa but in ways that are limited to ensure fairness and to curb the exploitation of African researchers.

Based on the document review, the responsibility for promoting solidarity-based action in H3Africa lies with four stakeholder groups: populations in LMICs; researchers in LMICs; researchers in HICs; and H3Africa funders. African researchers and research participants are expected to show their solidarity towards health for all, by allowing for the sharing of samples and data so as to allow for maximum research utility. Whilst HICs would show solidarity to African populations by funding genomics studies on African populations and building the capacity of African researchers to independently perform genomics studies. It is stated that the consortium embraces an ethos of the common good and therefore the consortiums research resource (samples, and data) would be used not only in Africa but also globally (H3Africa 2015).

Another demonstration of solidarity that could be deciphered from the review of the documents relates to patents, IP and subsequent access to proven interventions that may arise from the use of samples and data. The consortium argues that if care is not taken, IP claims may unnecessarily limit research and innovation. H3Africa adopts the NIH stance on IPs stating that *"H3Africa discourages any premature claims on precompetitive information that may impede research, though it encourages patenting of technology suitable for subsequent private investment that may lead to the development of products that address healthcare needs"* (H3Africa DARP). The H3Africa DARP takes this a step further and notes that the *"filling of patent applications and/or the enforcement of resultant patents in a manner that might restrict use of the H3Africa genotype-phenotype data could diminish the potential public benefit they could provide".* And in cases where this is unavoidable and for the purposes of innovation, *"preferential access [to*

intervention] be given to communities that contributed the samples from which the data in the H3Africa database is derived". Equally, users of samples and data are advised to opt for a non-exclusive license to LMICs should they determine that their innovation could provide solutions to Africa's burning health problems. (H3Africa DAA). This is ensure that LMIC populations have affordable access to the innovation and by extension, genomics technologies.

H3Africa policies are in line with the proposed Framework's principle of solidarity. They also speak to the principle of furthering the ideals of health justice (FIHJ).

5.3 Furthering the ideals of health justice (FIHJ)

The third requirement of the Framework speaks to the obligation of genomics research in Africa to further the ideals of health justice. That is, they should aim at reducing global health inequities. Generally, the argument for large scale genomics research projects in Africa has been fuelled by fears of a possible genomics divide that could widen global health inequities between LMICs and HICs (Gurdasani et al., 2015, H3Africa Consortium, 2014, Singer and Daar, 2001b). Global health research can further the ideals of health justice by: 1) ensuring that research addresses the health needs of worst-off populations; 2) building research capacity in LMICs and 3) promoting the translation and uptake of research findings.

In all the documents that were reviewed, there was recurred emphasis that genomics research in Africa "*should promote the goals of reducing global health inequality and exploitation of and strengthening the research system in the country where the samples are collected"* (Best practice guidelines). Below, I present how the three requirements of FIHJ were promoted by the H3Africa consortium.

5.3.1 Research priority setting

Research priority setting in global health research has the advantage of guiding research investment and by extension, ensuring that research is of potential public health benefit to study populations (Viergever et al., 2010, COHRED, 2000). Our framework requirement for the principle is that genomics research and biobanking consortia should prioritise diseases or health conditions that are a major contributor to the disease burden in Africa, have a genetic aetiology and for which genomics could provide maximum public health benefit.

The H3Africa research funding announcement (RFA) states that "*H3Africa is designed to provide new opportunities to African scientists to lead research on the genetic and environmental contributors to health and disease issues of importance to Africa through the use of genomics and other cutting-edge approaches".* The consortium's whitepaper also emphasises that H3Africa funders would "*support a number of focussed research projects that could address questions of*

significant scientific and medical importance to African Populations" or as would be later described in an article on H3Africa's approach to fairness, the *"H3Africa consortium seeks to harness genomics technology to investigate diseases pertinent to African populations.....and responsive to local health needs"(de Vries et al., 2015c).* Based on information on the H3Africa website, current projects span both communicable and non-communicable diseases including: tuberculosis, rheumatic heart disease, trypanosomiasis, stroke, respiratory infections, breast cancer, schizophrenia, sickle cell anaemia and neurological disorder. It is unclear how H3Africa decided on what diseases /health conditions to focus on, but the H3Africa White-Paper makes reference to the United Nations millennium development goals, as well as diseases that are a major cause of morbidity and mortality in Africa. There is also reference to WHO statistics on DALYs and mortality estimates in Africa, to justify why the consortium will also focus on chronic diseases. It is also stated in the White-Paper that following an agreement between the African Society of Human Genetics (AfSHG) and H3Africa funders, the consortium opted for a model whereby population genomics studies in Africa are tied to specific diseases. This is to ensure that these studies yield maximum benefit to African populations.

The H3Africa White-Paper specifically lists: tuberculosis; human African trypanosomiasis; cancer due to infectious diseases; sickle cell disease; hypertension; type 2 diabetes; stroke; cancer; and other Mendelian conditions (for example non syndromic deafness) as research priority areas for genomics in Africa. The list above contains diseases that are major drivers of morbidity or mortality in Africa and/or which may be considered diseases of the poor. Some diseases on the H3Africa's priority areas such as sickle cell disease and syndromic deafness may not be major contributors to the disease burden in Africa, however they have a strong genetic aetiology and genomics could therefore propose solutions with a high public health impact. The consortium also stresses the need for secondary users of data *to address questions of health importance to African and African diaspora populations"* (H3Africa White-Paper).

H3Africa research priority areas therefore align line with our framework principle for FIHJ that genomics research in Africa , including secondary uses of samples and data should prioritise diseases that are: a major driver contributor to the disease burden in Africa; have a strong genetic aetiology; and for which there is limited ability to ability to modify exposure to risk factors through environmental or life style changes; and which the use of genomics could have a high public health impact in resource limited settings. The data also suggest that research priorities for H3Africa were determined by African researchers and funders and this aligns with the framework's principle of shared sovereignty.

5.3.2 Research Capacity Building

A second requirement of the FIHJ principle is research capacity building. H3Africa acknowledges that the limited capacity for genomics research in Africa may worsen global health inequities (de Vries et al., 2015c). Research capacity building is a central component of H3Africa and is emphasized in all H3Africa governance- documents. The consortium adopted recommendations by the African Union and the New Partnership for Africa's Development (NEPAD) to build capacity for science and technology in Africa as well as public awareness of science (White-Paper). It hopes to achieve this through a multiplicity of approaches mainly: the training of African researchers (both senior and junior); skills development; support for genomics infrastructure; public engagement in genomics; and African leadership of H3Africa projects. These measures have the potential of creating equitable research partnerships and generating knowledge and interventions that are critical to addressing Africa's health needs. For example, the DAA states that *"H3Africa should support the training of Africans in the field of genetic epidemiology, bioinformatics, statistical analysis, high-throughput technologies, genomics data analysis, clinical research, and ELSI research to address current disparities in expertise and enable African researchers to participate fully in the generation, interpretation, and utilisation of data and discoveries from the samples donated".* This reliance on the recommendations from the African union and NEPAD highlights the role of this stakeholder group (policy makers) in decision-making

A highly desirable feature of consortia governance is ensuring that HIC partners assist LMIC partners with limited capacity to do independent research (Pratt and Hyder, 2017). To enable LMIC researchers carry out independent research, H3Africa funding is awarded directly to African researchers. Equally, the initiative has supported the establishment of African centres of excellence for genomics research and is funding the training of African researchers at multiple levels including: skills development; training of postgraduate and postdoctoral scientist (Munung et al., 2017). H3Africa data governance policies (DARP and DSA) also advocate for African researchers to be given priority access to samples and data. Collectively, and in the long run, this will definitely facilitate independent genomics research projects by African researchers. This also aligns with the Framework requirements that African researchers should lead genomics projects in Africa and that when researchers request to use samples and data, the DBAC and funders should prioritise those projects that involve African researchers as collaborators.

The capacity building component of the proposed framework also requires that African researchers should be supported to become independent researchers and that this is likely to happen through long term collaborations. The H3Africa program was initially set up as a 5 year project. The first round of funding ended in 2016. In 2017, a second call for applications was launched. Some of the projects in the first rounds phased out while others received a second round of funding, together with new projects. Overall, the consortium does not have a defined

mechanism for long term sustainability of genomics research on the continent or H3Africa projects. However, in the RFA, African researchers are expected to provide support letters stating how their institutions will ensure sustainability of projects as well as retain, where possible, junior scientists that are trained as part of H3Africa. In its White-Paper, the consortium also makes a call to African governments and regional policy organisations (such as the African union and NEPAD) to ensure the sustainability of genomics projects in Africa by committing funding for genomics research. This approach supports the Framework requirements.

5.3.3 Translation of research findings

The last of the three ways by which the principle of FIHJ could be advanced, is through having a mechanism for the translation of research findings and ensuring that study populations have access to proven interventions.

Overall, there is minimal reference to research translation in H3Africa consortium documents. Only two of the documents directly refer to translation. These are: the White-Paper and the governance and best practice guidelines. In the governance and best practice guidelines, there is a firm recommendation that *"efforts should be made to ensure that pertinent research findings are translated into population specific diagnostic assays/tests in cases where current and often Euro-centric assays/tests are inadequate in the African setting"* However, in the White-Paper, the consortium appears cautious in talking about translation stating that *"translation has been the greatest challenge of molecular genomics"* and that even though conventional studies are focusing more on identifying rare gene variants and their role in health and disease, *translating those findings into medical practice seems overwhelming at this point".*

Like most basic sciences, it is likely that it will take a while (including multiple studies) for the outcome of population genomics studies in Africa to be translated into clinical and /or policy interventions. This may explain why the consortium applies caution in talking about translation of research findings. While the proposed Framework requires that genomics research and biobanking consortia have a clear plan for the translation of research findings and for ensuring that study populations are able to access proven interventions emanating from these studies, H3Africaseems to be very cautious about discussing translation and did not detail what may happen in cases where products are developed from studies that use samples and data from H3Africa projects. However there is a general acknowledgement on the importance of public-private partnerships that could support translation of research findings. Also, the consortium encourages researchers to opt for non-exclusive licence to LMICs to ensure access to proven interventions *preferential access [to intervention] be given to communities that contributed the samples from which the data in the H3Africa database is derived* (section 5.2 "Solidarity).

5.4 Reciprocity

Reciprocity is the awareness that human interactions are contingent upon mutual exchange. The term reciprocity features in one of H3Africa's policy documents: *the best practice guidelines for governance of genomics and biobanking in Africa*. In the document, it is stated that the guidelines are informed, in part, by reciprocity and solidarity. Otherwise, expectations for reciprocal relationships range from: study populations opting to share samples and data from genomics research and biobanking projects in Africa with researchers in other parts of the world so as to contribute towards health for all; developing benefit sharing arrangements; acknowledging primary data producers; and research capacity building.

The first reciprocal relationship is between study populations and the global community. By participating in genomics research and biobanking projects, African populations are contributing Africa's rich genetic diversity to foster genomics research and genomics medicine globally. However, the consortium is called upon to ensure that that samples are not only exported out of Africa, for the global good, but that genomics research in Africa is *"responsive to the health needs of African populations, ……and that there is a stronger avenue for implementation of research findings into clinical practice"* (Best practice guidelines). This also applies to secondary uses of samples and data where requestors are expected to state how their studies will be addressing the health needs of African populations as well as how their projects would contribute to research capacity in Africa (White-Paper; de Vries et al 2015).

In terms of benefit sharing, the H3Africa *ethics and governance framework for best practice in genomics research and biobanking in Africa*, states that "*the main benefit of genomics research and biobanking should be health and welfare benefits to African populations as they are shouldering the research burdens and risk, [therefore] benefit sharing regulates that benefits are burden are distributed fairly and it is therefore key to ensuring that research collaboration is fair".* It also recommends that researchers *"disseminate information on genomic research and provide feedback of research results"* as this stands as a key benefit for African research participants.

The last aspect is acknowledging African researchers in publications arising from the use of H3Africa samples and data. The H3Africa whitepaper recommends the development of policies that will guarantee African researchers full credit for their primary work. This recommendation is reflected in the H3Africa DARP where is it stated that "*investigators who access H3Africa data [should] acknowledge the consortium and relevant project(s) appropriately in any oral or written presentations, disclosures or publications…..and intellectual property" as a way of "recognising the scientific contributions of researchers who generated the data"*

5.5 Transparency

Transparency is about openness and sharing of information in ways that are accessible and understandable to all stakeholders. It is about making available, information on the consortium's operations, policies and decision-making processes.

H3Africa policies are available through its website. Also the DBAC guidelines and DARP provide detailed information on the processes for accessing samples and data, as well as how request for access to samples and data would be evaluated. These two documents also state that the consortium will provide details of entities that have used samples or data from H3Africa projects. This information will be made available either to the public to the SC (See 5.1.7 Publicity). This aligns with our framework requirements for shared sovereignty that information on how samples and data have been used should be made publicly available to all affected stakeholders.

Transparency however does not only apply to decision-making processes. It is also about providing detailed and comprehensible information about the consortium's activities to study communities. The H3Africa informed consent guidelines state that *"it is important that the development of a consent process is informed by a wider community engagement effort aiming to meaningfully engage with prospective research participants and their communities to identify and discuss the ethical aspects of the research".* Also, one of the three capacity building approaches in H3Africa, as stated in its White-Paper is public engagement. Though not much said with respect to public engagement, some projects on public understanding of science projects (Mboowa et al., 2018) as well as community engagement (Staunton et al., 2018) has been ongoing within the H3Africa consortium. This shows that the Frameworks recommendation for transparency and accountability could be implemented. There was however no information on whether and how the consortium will inform other stakeholders (excluding funders) of how it is achieving its equity oriented goal of preventing a genomics divide in Africa.

5.6 Shared resources

The shared resources component of the Framework demands that consortia partners should receive a fair share of the consortium's resources and that the bulk of it should be allocated to the African partner. Also, stakeholders should contribute resources based on their wealth. Four major kinds of resources could be identified from H3Africa governance-related documents: human resources; samples and data; financial resources and patents/intellectual property. Table 8, provides a description of these resources.

Table 8: Resources in genomics research and biobanking in Africa

Resource	Description of how resources will be used
Samples	To be shared globally for use in research that could improve global health. Material transfer agreements provide fair terms of exchange and the idea is to minimise the possibility of exploitation of African researchers and study population
Data	Data generated from H3Africa projects will be made available to researchers via the European Genome Archive. A data sharing agreement between the data and sample provider (H3Africa or H3Africa PI is mandatory). Access to H3Africa data must be approved by the DBAC. Indicating that while it is available for use by researchers around the world, it will be controlled and not freely available.
Financial resources	Funds for H3Africa projects would be held by a researcher affiliated to an African institution. Majority (51%) of the funding is to be spent in institutions in Africa.
Research publications	There is a nine months embargo period to allow primary data producers to analyse and publish their findings before the data is made available via the European genome archive Primary data producers should be acknowledged in all publications emanating from the use of their data. The H3Africa coordinating centre will track publications to ensure that primary data producers and the consortium are acknowledged.
Intellectual property and patents	Awardees will retain copyright for software developed as part of awards. Patents that may limit research use of data is discouraged. When the outcomes of study that used samples and data from H3Africa leads to tangible products or services, innovators are encouraged to opt for non-exclusive licences

	so as to ensure that study communities have access to the health intervention.
Research Infrastructure	Laboratories, research equipment, centres of excellence, biobanks. African institutions will provide infrastructural support for projects. H3Africa will support the development of African centres of excellence for genomics research. Infrastructural development will be guided by a needs assessment of what already exist in the continent.
Human resources	Researchers, administrative staff, funders, clinical staff Majority of project partners (co-PIs) are to be based in an African institution.

One of the key recommendations for promoting justice in global health research consortia is that stakeholders should contribute resources based on their wealth and that the majority of resources should be assigned to the LMIC partner as this allows them to carry on research that is of relevance to the health needs of their populations. In terms of funding, the main funders of H3Africa, the NIH and Wellcome trust, are institutions in HICs. H3Africa projects are led by researchers based in African institutions and funding is directly allocated to their institutions. Of the total funding, at least 51% has to be used in an African institution (RFA-Research). Also, the overall expectation is that H3Africa will seek ways of ensuring that the research partnerships are structured such that African researchers have *"preferential access to samples and data"* (de Vries et al., 2015). The H3Africa MTA also emphasises the need for African researchers and institutions to retain ownership of samples and data and this has implications for intellectual property and the filing of patents. H3Africa largely follows recommendations that global health research consortia assign more resources to the less resourced partner. Therefore, it can be said that these policies are consistent with the principle of shared resources.

5.7 Mutual Trust

Trust is a relational concept and is based on the expectation that one can rely on another person's words or actions and that the person has good intentions to carry out their promises. (Bligh, 2017). Trust is also a necessary requirement for solidarity and has great value in instances where one party is vulnerable to the other and therefore at risk of exploitation by the more influential

party. In our governance framework we had suggested that trust could be fostered in genomics research through long term collaborations, recognising the contribution of each stakeholder group and through public engagement activities.

Statements in H3Africa documents on the importance of building trust between stakeholders suggest that trust is required at two levels: trust between African researchers and their collaborators in HICs and between study communities and African researchers/research institutions. For the former, the consortium hopes that trust could be built through fostering equitable relationships between HICs and African researchers (de Vries et al., 2015c). This has the advantage of countering fears of exploitation of African scientist. In terms of trust between study participants or communities and African researchers and institutions, it is hoped that trust could be built in three major ways: community engagement, return of results and re-contact with research participants (Best practice guidelines and RFA research). Concerns of exploitation of African populations and researchers may perhaps explain why only these three group of stakeholders and not the others, were specifically targeted as stakeholder groups for which it is important to build trustworthy relationships, It also shows that reciprocity-based actions, respect for values and norms of African populations, and accountability are necessary for building trust. H3Africa policies therefore support our framework principles of trust and by extension, reciprocity, shared decision-making and accountability.

5.8 Shared Responsibility

The shared responsibility principle demands that responsibilities should be assigned to stakeholders based on the function that they typically assume. In H3Africa activities and decision-making are likely to happen in groups, for example: WGs, steering committee, the DBAC and the IEC. A look at membership in the different groups or committees identifies the following stakeholders: African researchers, data experts, bioethicists, fraternity persons with legal expertise, study populations, funders, researchers in HICs and members of ethics committees. Other stakeholders, in genomics research in Africa who may not be part of the consortium but who are sometimes referred to in the documents are: study communities; European nucleotide archive; European genome archive; commercial enterprises and journal editors. Table 9, shows the different stakeholder groups in H3africa and their corresponding responsibilities as per H3Africa governance documents.

Table 9: Roles and responsibilities of different H3Africa stakeholders

Stakeholder	Roles and responsibilities
Researchers in Africa	• Outline how their work will contribute to reducing global health inequities • Be involved in community engagement activities with the goal of building trust between study communities and researchers • Identify research priorities that are relevant to study populations • Make publicly available resources that are developed with the use of H3Africa resources • Take part in key decision-making • Provide scientific and technical leadership for projects
DBAC	• Provides oversight of data collected and/or generated by H3Africa projects. This includes review of request for access to data • Gives feedback on approved request for data use to RECs that approved the primary studies
Steering committee	• Made of H3Africa PIs (African researchers) and funders • Major decision-making body of the consortium. • Advices stakeholders of major project related activities
Collaborating researchers in HICs	• Support capacity building efforts of the consortium especially in projects where the serve as co-P.Is or collaborators
Funders	• Research priority setting • decision-making (steering committee) • funding for H3Africa projects

	• monitor and evaluate projects through a peer review process (with inputs from the IEC)
African research institutions	• Provide infrastructural support for H3Africa projects. • Make a commitment to share samples and data from H3Africa projects. • Provide logistic and administrative support to H3Africa projects. • Organise community engagement activities, in line with cultural and context specific dynamics, with the goal of building trust between research institutions and study communities. • Ensure sustainability of projects and retain, where possible, junior scientist trained as part of H3Africa
Policy makers/national governments	• Ensure sustainability of projects • Provide research infrastructure for approved projects
Regional networks and organisations	• Sustainability of genomics research through the provision of funding.
Research Ethics Committees	• Safeguard the interest of research participants. • Provide oversight of samples, with the aim of ensuring responsible use of samples for future studies.
Independent Expert committee	• Review and evaluate the progress H3Africa • Advice funders on the progress and achievements of the consortium. • Participate in key decision-making (as part of the steering committee) but with non-voting rights.
Program Scientist	• Negotiate program goals with H3Africa PIs • Participate in decision-making (within the steering committee) but with non-voting rights.
Healthcare professionals (medical geneticist, physicians, nurses, phlebotomist, nurses)	• Feedback of genetic findings

	• Develop guidelines for the feedback back of incidental findings • Management of patients. • Sample collection and identification of phenotypes.
Secondary users of samples and data	• Ensure that their proposed studies contribute to efforts aimed at reducing global health inequities. • Submit annual reports to the DBAC stating how they have complied with the DAA.
Research communities/Research Participants	• Primary resource for samples and data. • Maybe involved in decision-making (as part of DBAC).
H3Africa coordinating Centre (based at HIC and an African research institution).	• Monitor use of data and samples. • Advice secondary users of samples and data on access procedures. • Provide administrative support to the consortium.
European Genome Archive European nucleotide archive	• Store data generated from H3Africa projects. • Make data available following approval from the DBAC.

Shared responsibility demands that the responsibility for stakeholders should follow the functional requirement principle that is stakeholders should be assigned responsibilities based on the function that they would typically assume (see section 2.2.2b). The roles and responsibilities assigned to the various stakeholders by H3Africa fit with the with the functional requirement principle, and therefore with the Framework requirement (Chapter 3; table 4). The document review however reveals stakeholders such as the European genome archive, which was not included in our governance framework. However, the framework had broadly indicated that African research institutions would ensure that data is submitted to the consortium's database, without specifically mentioning any genomics database. On the other hand, the framework includes RECs and journals, which are not assigned specific functions in H3Africa documents, although reference may have been made to them. For example, the DBAC is expected to draw the attention of journals in cases of breach of data use (H3Africa DARP). This is certainly in the hope that journals will withdraw these articles or ask authors to comply when possible. The DBAC is also expected to communicate RECs who provided initial oversight of

samples and data to inform them of how samples and data have been used (Best practice guidelines). These responsibilities of the DBAC and scientific journals where not captured in the proposed Framework. It will be considered when revising the Framework.

5.9 Mutual Collective Accountability (MCA)

Mutual collective accountability (MCA) is the last principle promoted in our framework. Three things are key in MCA: identifying benchmarks for measuring success; participation of all stakeholders in setting and evaluating benchmarks (process, output, and outcome indicators) and publicity of decisions. Also key in MCA is monitoring and evaluation, and the principles of transparency and trust.

The H3Africa best practice guidelines for the governance of genomics research and biobanking recommends that the *"impact of community engagement efforts should be evaluated".* However it is not stated how this will be done and by who. It is also stated that H3Africa would be evaluated after five years (RFA-Research) and the following are listed as indicators for measuring the consortium's success: publications in high impact journals; first and senior authorship by H3Africa investigators; operation of a pan–African bioinformatics network, operational biorepositories; availability of funding for genomics projects, reversal of brain drain (H3Africa 2014, White-Paper). These indicators and benchmarks for success are published in documents that were jointly written by African researchers and H3Africa funders, suggesting therefore that these two stakeholder groups decided on how the success of the consortium will be measured. The IEC is expected to regularly advice project funders on the progress of the consortium, though it is unclear if the IEC will be using the stated benchmarks.

Monitoring and evaluation is a necessary pre-condition for accountability. Three major H3Africa activities will be monitored: 1) project outcomes, 2) community engagement activities; and 3) access to samples and data (best practice guidelines and DBAC guidelines). The Chair of the DBAC is expected to submit an annual report to the steering committee. The DBAC is expected to *"communicate regularly with the ethics review committees with primary oversight of the samples and data being overseen…….this enabling the ethics committee to know what is happening with the samples"* (Best practice guidelines). One can therefore say that secondary users of data are accountable to the DBAC and the DBAC is accountable to the primary ethics committees and the steering committee. While the researchers are accountable to the ethics committees and to study communities.

The best practice guidelines further recommends that the consortium should monitor the use of samples, including: number of samples exported; recipients of the samples; reasons for exporting samples; number of archived or destroyed samples. The H3Africa coordinating centre will also

"keep records of who gain[ed] access, and when, to ensure that the terms of access and the conditions of the publication embargo are complied with" (H3Africa DARP). Secondary users of data and samples, on the other hand, are expected to submit annual reports to the DBAC stating how they have complied with the DAA. Secondary users are therefore directly accountable to the DBAC. It is only this level (secondary users to DBAC) of accountability that has an enforcement mechanism in place, which is the suspension of access to data (H3Africa DARP). Equally, *future access may also be denied to individuals found responsible for a previous breach of the conditions of the DAA".* And in the case where the publication embargo was not respected *the "H3A steering committee or DBAC may contact the appropriate journal editor with evidence that data use conditions have been breached and to request that any manuscripts be withdrawn"* (H3Africa DARP). This would suggest that the consortium has to work together with publishers or journal editors to define processes and agreeable reasons for withdrawing a published article.

It is also expected that H3Africa, through the coordinating centre, will track publications arising from the use of H3Africa samples or data. This is to ensure that the consortium is being acknowledged in studies that use H3Africa data and also that the nine months publication embargo has been respected (H3Africa DARP). This is important as it may be considered a way of checking concerns of "helicopter research" whereby sample collected in Africa are exported to HICs and African researchers who collected the samples are not involved in the data analysis and publications, nor are the provided with information on how and what samples are being used.

TheH3Africa consortium policies support the MCA principle, as there are indications of stakeholders being accountable to each other. However, there is the absence of accountability mechanisms to other stakeholders such as study communities and policy makers in Africa. That is would, study communities and policy makers be informed of how the consortium is achieving its equity oriented goals. H3Africa also seems to have adopted the use of an independent expert committee to advice the consortium on whether or not it is achieving its set goals, thereby bringing in accountability to an external body.This is permissible in MCA as long as the responsibilities of stakeholders are clearly defined.

5.10 Points of divergence between the governance framework and H3Africa governance related documents

Overall, the document analysis showed that most of H3Africa policies broadly align with all the principles promoted in our framework, except for certain specific cases. In some cases, the documents provided recommendations which were not included in our framework, but this was mainly in terms of practical implementation. A case in point is the shared responsibility principle, specifically the responsibilities assigned to the DBAC, scientific journals, and the independent

body for monitoring and evaluation (section 5.8). Also, the H3Africa best practice guidelines mentioned the need for respectful and harmonious relationships especially with study communities (section 5.1.3; Relevance). This was not captured in the framework and was therefore considered as a possible points of revision (reflective equilibrium).

5.11 Chapter Summary

I have presented an analysis of how H3Africa policy and governance related documents align or diverge form the key principles for promoting fairness and justice in genomics research and biobanking in Africa, as articulated in our proposed governance framework (Chapter 3). With a few exceptions on requirements for shared responsibility and MCA, the majority of the proposed Framework requirements already constitute part of governance of H3Africa. An indication that it is likely to meet the expectations of all stakeholders and that the Framework's recommendations could be practically implemented.

In the next chapter, I report on the analysis of the in-depth interviews. The interviews investigate if H3Africa stakeholders consider the frameworks principles as important in promoting justice and fairness in genomics research and biobanking.

Chapter 6: Stakeholders' Perspectives on Governance Requirements for Genomics Research in Africa

In Chapter 5, I presented an analysis of H3Africa governance documents. The aim was to explore how the principles advocated for in the proposed governance Framework are upheld by the governance practices of H3Africa and if there were any points of divergence. In this chapter, I will present the analysis of the in-depth interviews conducted with H3Africa stakeholders. The aim of the interviews was to test our framework's principles against the expectations of the different stakeholders in genomics research in Africa. That is to explore if their expectations of governance are similar to that proposed in the Framework or if there were points of divergence that should be considered (reflective equilibrium).

Fifteen (15) in-depth, one-on-one interviews were conducted with members of the H3Africa consortium who have been involved in developing governance policies for H3Africa. Interviewees belonged to one or more of the following stakeholder groups: researchers, funders, REC members, policy makers, IEC and the DBAC. The interview transcripts were thematically analysed according to the principles described in our proposed governance framework. In presenting the results, I will also simultaneously discuss the results and provide an interpretation where necessary and then state if the intuitions of the stakeholders align or diverge from our framework's principles which include: shared sovereignty; solidarity, furthering the ideals of health justice (FIHJ), reciprocity, transparency, shared resources, shared responsibility, mutual trust and mutual collective accountability (MCA).

6.1 Shared Sovereignty

In the interviews, I prompted researchers to reflect on some of the decision-making processes that they have been involved in, within H3Africa. This involved questions around who was involved in the process, what approaches where used, if they thought they voices of all stakeholders were taken into consideration. All interviewees were of the opinion that processes to develop H3Africa policies had to a large extent followed a consensus-driven deliberative process but that the process could be improved. This was because, they felt that in some cases, the policies may have been influenced by more influential stakeholders, most likely the funders. There was also agreement that deliberative and consensus driven dialogue should be the ideal process for developing ethics and governance policies. For some of the interviewees, deliberative processes are a show of respect and indicate that no one stakeholder group is dictating what

needs to be done to their African partners. Below, I present the different expectations for shared sovereignty as per the interviews.

6.1.1 Consensus driven deliberations

In the framework, we had recommended that decision-making processes should be deliberative and that decisions should be reached via consensus. Overall interviewees were of the opinion that in developing H3Africa governance policies, consultations were done with different stakeholder groups, either through face-to-face meetings and or/ electronically, and that this allowed for some degree of deliberations. There was also a parallel view that certain stakeholder groups (research participants and policymakers) were left out of the decision-making process. Overall, the processes were considered fair and transparent.

> *I think it was not a rushed process. It was a process which was structured in a way that there were a series of discussions and consultations of the different drafts that were developed. I think it was a fair process, given the stakeholders who were already involved. We have already said that some stakeholders may have been left out. There was transparency, there was discussion, and there was openness. (Ntube)*

One of the downsides of deliberative decision-making is that it is time-consuming and requires a lot of resources. We asked interviewees if this is not sufficient to avoid deliberative processes, and if so, what other decision making processes could be ideal. There was agreement that deliberative processes take a lot of time but that it was a necessary when new policies and governance mechanisms are being developed.

> *Well, it has to be resourced, it is time-consuming, but when you are doing something that is new, you are introducing new concepts, I think ultimately it is ethically the only sound way to do it….. So what feels like a slowing down of the process, initially, will actually create better research ultimately. …..I do not think you have to do that level of ethics deliberation for everything, some things are much simpler, but this was all new and complex and ethics committees had no training in most of this stuff. So it is unfair to expect them to make decisions on things that they know very little. (Nxumalo)*

Deliberative processes that are inclusive and consensus driven were therefore considered to be good way of reaching decisions, especially when new ideas and policies are being discussed. This aligns with our framework's requirements for deliberative decision making.

6.1.2 Inclusivity

Inclusivity requires that all stakeholders who may be affected by a decision should be included in the decision-making process. Requirements for inclusivity include: Breadth (mass and range) and qualitative equality (See section 2.2.2d Inclusiveness).

6.1.2a **Breadth**

The steering committee (SC) the data and biospecimen access committee (DBAC) and the working groups (WG) are the main decision making structures in H3Africa. The composition of these governance structures varied depending on their activities but stakeholder groups that mainly involved in decision making include: African researchers, HIC researchers, funders, RECs, and in the case of the DBAC, a community representative. We also noted in the analysis of H3Africa governance documents that decision-making within H3Africa is dominated by three stakeholder groups: IEC (mainly HIC researchers), funders, IEC and African researchers. We asked interviewees if there were any stakeholder groups that should have been included in decision making but were often left out were left out of decision-making processes. In response to this, interviewees mentioned study communities and argued that it was important to include them in decision making because there should be "nothing about them, without them"

> *The group of stakeholders that I can say was missing from the process of developing the framework is the group of ordinary potential participants in genomic/genetic research. It is important to include this group of stakeholders under the fairness slogan that states: "Nothing about them without them" (Zoya)*

A major dilemma for most interviewees however was the appropriate method to be used for engaging this this stakeholder group and how the representatives will be selected considering that that research participants for population genomics studies are often recruited from several "communities".

> *But when we talk of a community member, what community are we going to pull that from? Is it a community member who is part of a life project, which could be just one project? So certainly we should have given a voice to a particular community and I don't think it would have been a disservice to the process at all. If anything it would have enhanced the process. But I am just trying to figure out how would they be involved (Palesa)*

Some interviewees suggested it may be best to involve study communities in decision-making at the project level, especially where organised patient groups exist. Other proposals included: allowing RECs to represent the interest of study participants; and developing public engagement activities that seek the opinion of the public on certain genomics research policies.

Whilst including a wider range of stakeholders in decision making is important, it should be done in such a way that no one stakeholder group is disproportionately represented. This is to ensure that no one stakeholder group dominates decision-making by virtue of numbers. I asked interviewees if the decision-making processes in H3Africa were, in any way, disproportionately influenced by a certain stakeholder group. Some interviewees mentioned that stakeholders from HICs have had a major say in decision-making compared to the African stakeholders.

> *The reality is that the power still resides out of Africa. If we are going to take this view that is very democratic and you have got two African researchers in a group of 7, the power struggle is there. ….. So it doesn't matter how much voting you are going to take. So I think that the way that it has worked in some projects is for Africans to actually be the PIs. So immediately you shift power, you shift not only the power but you shift people's understanding of what is at stake (Kofi)*

Some of the interviewees said this shift in power dynamics has and has actually seen African researchers take more control of decision-making. Although occasionally the funders would want to have a major say in a particular decision

> *The steering committee is composed of the PIs, and the steering committee is where the decisions are made on governance documents. So basically I think they handed the power to the PI's, and they took that on…..So I think it is that policy that the PI had to be African. And the second bit of that is, making sure that the ones in charge of the governance are the PIs. That gives them the say and a shift in direction. I also think over time their voice became stronger, once the funding was in place, once they started feeling their way and finding their voice. I think the dynamic of power has shifted. I think the funders originally said a lot more and were more in control and they still occasionally wave the funder stick, but I actually think that the steering committee has found its voice and has worked. (Nxumalo)*

We also asked interviewees which stakeholder groups, in their opinion, was more powerful and therefore likely to influence certain policies in their favour compared to other stakeholder groups. It was suggested that this were mainly funders and researchers from HICs.

> *I always did have slight concerns about the roles of funders in the decision on broad consent for example. The potential influence of funders is huge in developing a governance framework and it's how you balance that. That will always be the problem. (Palesa)*

Such an imbalance could be addressed through research capacity building and the equitable sharing of research resources.

There are groups that probably have more power because they have more money or more resources, it is always like that, not just in Africa. But what could be leveraged on the other side where they do not have money or resources is to give them more education more information and build capacity (Sanyu)

The interviews and document analysis suggest giving power to the less influential stakeholders, building their capacity, and where possible, assigning more resources to them. These different ways of minimising the a disproportionate influence over decision making by a particular stakeholder group powerful stakeholders on decision-making and in achieving a fair research collaboration is in line with the FIHJ principle.

6.1.2b <u>Qualitative Equality</u>

Qualitative equality is about ensuring that deliberations occur in a democratic environment, i.e. each stakeholder group is not just represented, but has a chance, through reasoned argument, to equally influence the final decision. The document analysis showed that the development of some policies, especially by WGs, met the qualitative equality requirement. In the interviews I asked our interviewees if the qualitative equality requirement was achieved during decision making processes in H3Africa.

I think it was a collective process. I think that whatever views were expressed, it was done in a collective manner so again. I don't feel after having read the document that I was strongly in disagreement with anything. So I think that my views will probably be reflected in the document but through a collective process and not through an individual process. (Diarra)

The document analysis showed that the Ethics and Regulatory Issues WGs had consulted non-H3Africa members when developing some H3Africa ethics and governance policies. The question therefore was whether consulting other stakeholders was appropriate and important. Some interviewees felt that consultation of a wide range of stakeholders improved the deliberative process. They were also of the opinion that consultation is part of decision-making in traditional African settings and should be adopted in decision making in global health research.

I would say that it is a deliberative process in that there was back and forth movement in terms of discussions. You know, during the calls, people have the opportunity to ask questions and to ask for guidance from experts….. If you look at a lot of our African communities, we actually have our traditional leaders, but our traditional leaders do not make decisions alone. They actually consult. They've got a group of elders who work with them, they consult those elders, that is actually go down to the lower levels and then they consult the

lower levels when they meet they consult amongst themselves and then they advise the leader (Chishala)

Consultation therefore forms an important part of decision-making in African settings. In the framework, we had suggested that the views of stakeholder groups who are not traditionally involved in decision-making within the consortium (e.g. study communities and policy makers), could be captured during community or public engagement activities. Consultation seems to be one of the methods of achieving this and could be incorporated as part of public engagement activities.

6.1.3 Relevance

Another requirement for shared sovereignty is that decisions should appeal to the values and norms of the different stakeholders that may be affected by the decision. In the interviews it emerged that in developing some governance policies for H3Africa, there were calls for governance should be cognisant of values and principles that are upheld in most African settings.

There were also issues of the need for any such governance regime to be able to promote respect for communitarian values that are reflective of the nature that a number of African cultures and settings. (Eyadema)

This lends support for our choice to adopt principles from *Ubuntu* that were not necessarily promoted by the two other accounts of global health justice and governance (SHG and GGH).

Some interviewees also suggested that decision-making processes should not only align with the norms and principles considered important by all affected stakeholders, but that it should also take into account the historical reasons that underpine certain decisions in genomics research and biobanking in Africa.

One [governance] that is built on mutual respect and trust. One that is beneficial to both parties, one that is cognisant of the needs and principles that underpin the historical need for this process. (Palesa).

One of the underlying reasons for calls for justice and fairness in genomics research and biobanking consortia in Africa has been the historical experiences of exploitation of African researchers and study populations. The quote above suggests that in designing governance mechanisms, genomics research and biobanking consortia in Africa should actively seek to promote policies that will minimise the chances of exploitation of African researchers and research participants.

6.1.4 Conflict Management

Conflict management is a key requirement for shared sovereignty. The document analysis showed that conflict management was mainly discussed in terms of the workings of the DBAC and that this may require use of an ad-hoc committee. From the interviews, it transpired that there hasn't been any conflict at the level of the DBAC or in the development of policies that required conflict resolution by an independent body. It was therefore not possible to explore if the use of an ad-hoc or independent body worked better in conflict resolution. However, some of the interviewees felt that deliberating and reaching consensus is one of the best ways of resolving conflict.

> *I think it (consensus driven dialogue) minimises conflict. In ethics, people have very strong views, and that is why I think it can take some time to come to a consensus on the best approach in terms of ethical governance for example. But I think it gives everyone a chance to express their views, and then the ultimate product in terms of guidelines, can say where there is flexibility to adjust to local conditions or local views. So I think that, that is the approach that best promotes both the science and minimises conflict. (Kinela)*

This seems to suggest that in the case where an entity such as the ad-hoc committee is used to resolve issues of conflict, the process should be deliberative and a solution reached via consensus. Like all decision-making structures, the composition of the ad-hoc committee should be such that each stakeholder has an equal chance to influence the decision making process.

6.2 Solidarity

Solidarity based actions would require that genomics research in Africa: further the ideals of health justice (FIHJ); that samples and data be shared broadly; and that benefit sharing mechanisms are available. Our analysis of H3Africa governance-related documents showed that there was a call for HICs to show solidarity with populations in Africa by supporting genomics research in Africa so as to prevent a genomics divide between Africa and HICs. There was also a call for solidarity from African populations to the global community in terms of allowing for broad sharing of samples and data, so as to facilitate genomics variation studies that would benefit populations worldwide. We will present the views and expectations of interviewees in relation to using genomics as a tool to addressing global health inequities in section 6.3 (Furthering the ideals of health justice (FIHJ).

In terms of sharing of samples and data, H3Africa policies support the sharing of data and samples with other researchers and entities from around the world for the purposes of research and innovation. However, this will be done through controlled access, via the H3Africa DBAC. The

intention for controlled access is to minimise exploitation of African scientist whilst also allowing maximum use of samples and data by African scientists. When interviewees were asked about their views on broad sharing of samples and data, the responses were in support for maximum sharing of samples and data and solidarity-based reasons were often cited as the reason why they will support the broad sharing of samples and data.

> *Solidarity is used a lot in terms of fighting a common threat. So you have this image of people standing shoulder to shoulder supporting each other. So reciprocity goes with all of that; so if I support you, you will support me and so forth. So I think in the context of genomics research, what reciprocity could mean, is that if research participants are willing to not only participate in research but share data, then there should be a reciprocal sharing of data back. (Kinela)*

The quote above, which is similar to views expressed by other interviews highlights reciprocity-based-solidarity, which is a common feature of African communitarianism. Furthermore, it shows a link between the principles of solidarity and reciprocity. It was therefore common for interviewees to suggest that the requirement for broad sharing of data should also be accompanied by requirements to prioritise research on health conditions prevalent in the study communities and that is done in collaboration with African researchers.

> *Access can be made open to all researchers regardless of institutional base, so long as they are working on health conditions affecting African populations and/or working in collaboration with scientists based in African institutions. (Eyadema)*

Although concerns of exploitation in global health research may have over the years led to a nervousness by African researchers to share samples and data, the interviews suggest that there is growing willingness to share data, in as much as African populations and researchers benefit from the process. The major concern therefore is not about open sharing of samples and data, rather it is more of an expectation of reciprocity, one which ensures that all stakeholders harness some degree of benefits.

There was also the view, based on *Ubuntu* values, that the sharing of samples and data between African researchers is likely to be easily accepted by group of persons who share a common value or who trust each other. This would mean that the sharing of samples and data would be easier between trusted collaborators and between African researchers compared to sharing between researchers with no established and trusted relationship. As one interviewee explained, *Ubuntu* is stronger within people who share a common value.

> *Ubuntu is probably strongest within an ethnic group and then gets weaker and weaker as one moves out from the ethnic group. So as you well know, someone is more likely to be impartial to do something within an ethnic group, and less inclined to do something across ethnic groups, and then obviously less inclined to do something across international borders (Sankara).*

This solidarity with other African researchers or with a trusted collaborator may have been enhanced by previous experiences of parachute research. More so, it highlights the importance of the principle of mutual trust and how it relates to the principle of solidarity.

> *Whether you are from Africa, Asia or Europe, you are a human being. And therefore we are trying to advance the science of humanity and the understanding of health and humanity. But at the same time, you do not want to be the person that is practicing Ubuntu, where you are giving away your samples to someone who has no understanding or idea of what Ubuntu means, and is going to take advantage of you…..I think Ubuntu could work provided everybody is on the same page. Similarly, if you want to decide on a hierarchy of access, then you would possibly say that an African requestor would be viewed more favourably than a non-African requestor, so that priorities are given to regional collaboration rather than international collaboration, with a view to build regional capacity. (Sankara)*

This suggests that priority for access to samples and data should be given to H3Africa researchers and then to African researchers or to collaborations that involve African researchers. H3Africa's data access policies promote priority access to samples and data by African researchers, especially for the primary researchers. Therefore, controlled access to samples and data as suggested in our framework, seems to be an approach that is supported by stakeholders involved in research as the ethical thing to do at this time.

6.3 Furthering the ideals of health justice (FIHJ)

The third principle in our framework is furthering the ideals of health justice (FIHJ). The rationale for including African populations in genomics research and biobanking has already been described in previous chapters. This includes, broadly, a scientific imperative and an ethical imperative. The scientific imperative is based on the importance of capturing the diversity of the African genome so as to inform current global understanding of: differential susceptibility to complex diseases; response to pharmacological agents; and the interplay between genetics and the environment. The ethical imperative is based on fears that failure to include African populations in genomics research could lead to a possible genomics divide and further exacerbate global health inequities. Whilst there is a widely held view that genomics holds

promise in improving healthcare, it must be performed in a particular way to address global health inequities.

As stated in the Framework, for genomics research have a responsibility to prioritise health conditions that are a major contributor to the disease burden in worst-off populations; build research capacity for genomics research; and have a plan for the translation of genomics research findings to clinical interventions or policies which would then be made accessible to study populations.

6.3.1 Research priorities for genomics research in Africa.

The Framework recommends that genomics research in Africa should focus on diseases that are a major contributor to the disease burden in the study population, and for which genomics is likely to provide significant public health benefits. This also applies to secondary uses of samples and data. In the interviews, I asked different stakeholders how they expect genomics research in Africa to address global health inequities. Overall, they were of the opinion that genomics research in Africa would not only address health issues of benefit to African populations but would also be of benefit to non-African populations. However, in selecting research priorities, emphasis should be on addressing the health needs of African populations especially those that are a major contributor to the disease burden.

> *I think it is important that research that is done on African populations has, at least, a good probability of improving health in Africa, for example by establishing the genomic basis of particular disease conditions which hopefully will lead to better therapies in the future. Now, my understanding is that research in H3Africa, which is what I am familiar with, has already identified new genetic variants that were not known before. Those of course are not only helpful for African health, but are important for the global community as well. But it certainly has been the case that there are severe global health inequities and imbalances that need to be redressed in terms of poorer life expectancy, for example, in certain parts of Africa. It is important that the research that is done, has the possibility of leading to outcomes which will improve that situation, which will advance the overall goal of greater health equity across the globe. (Kinela)*

The emphasis seems to be that population genomics studies in Africa should be tied to particular disease conditions. Interviewees did not refer to specific diseases, but opined that it should be diseases that disproportionately affect African populations.

> *We know that there are some diseases that clearly affect African or poor countries in a disproportionate manner. So I believe our energies should also be more focused in those areas. So by addressing those diseases of poverty*

affecting African countries, we are trying to improve the health conditions of the people. (Chishala)

Despite the proposal to focus on diseases that are a major contributor to the disease burden, it was also echoed that setting priorities for genomics research in Africa is not very straightforward. It would require that not only prioritising health conditions that are a major causes of morbidity and mortality, but those ones for which for which genomics studies are likely to yield more knowledge or lead to new health interventions.

I would want to prioritise what is important for Africa. But in order to determine what is best for Africa, it's not that simple. It is not simply the common disorders that we have on the continent but those disorders which would give the best investment in terms of the knowledge they generate, which could result in the development of preventives, diagnostics or therapeutics that would benefit people on the continent. I would not necessarily just go for the common disorders. (Diarra)

Despite the dominant suggestion to focus on diseases that are a major contributor to the disease burden in African populations, an exception was made for rare genetic diseases. The reason being that leaving out this these category of health conditions will be a missed opportunity to develop interventions for rare genetic diseases, especially as these diseases could also serve as models for understanding certain pathologies and developing interventions for them.

But one would say a very interesting category of diseases, which is certain rare disorders, and if you were just going for the common disorders, you would then not allow research to happen in these rare disorder. These rare disorders very often would require critical information on for example signalling and other pathways which can allow for rational drug design and for the development of very specific agents, which would not have been developed had one not focussed on these rare disorders. (Diarra)

The interview data demonstrates that selecting a research target may be very complex for genomics and will require that consideration be given not only to the disease burden, but to other factors such as evidence of genetic aetiology and the cost benefit ratio compared to other interventions. Also, it may be difficult to determine at an early stage what diseases are likely to benefit more from genomics interventions, except for single gene disorders. A view that is shared by some genomics researchers in Africa (Munung et al., 2018). This supports the proposed Framework's requirement for research priority setting.. However, the proposed framework did not cover the inclusion of rare genetic diseases. Rare diseases are health conditions with a low prevalence of less than 5/10,000 (Montserrat Moliner and Waligóra, 2013). They are often

chronic, lifelong and present in diverse ways including a range of physical and neuro-developmental manifestations, and mental health disorders such as depression, psychosis and anxiety disorders (de Vries, 2017, Montserrat Moliner and Waligóra, 2013). It is estimated that 8% of the global population present with rare genetic diseases, a majority of which are single-gene diseases. Given the Mendelian pattern of inheritance of most rare genetic conditions, rare diseases provide a good model for understanding genetic mechanisms for diseases. However, given the fewer number of persons with rare genetic diseases, biobanks and registries that could support genetic studies on rare diseases and hopefully lead to improved clinical management for persons with rare genetic conditions. I will therefore revise the framework recommendations to include rare diseases as a priority area for genomics research and biobanking in Africa.

6.3.2 Capacity Building

The second requirement for FIHJ is to build the capacity of genomics research in Africa, so as toenable LMICs to generate their own research evidence. This requires that capacity building should be evidenced based, takes place at different levels (project, institution and national level), and over a longer period of time, until such that African researchers have the capability to conduct independent research. Research capacity building should involve: technical and financial assistance for genomics research in Africa; coordinating the activities of the different actors (to minimise redundancies); and empowering individuals and groups that are engaged in genomics research and biobanking in Africa. The analysis of H3Africa governance-related documents document shows that capacity building is at the core H3Africa projects and the focus has been on infrastructural capacity building, training of African researchers at different levels (Masters, PhD and skills building) and African leadership of genomics projects.

Interviewees also mentioned that research capacity building is an integral part of H3Africa projects. It is hoped that the capacity building efforts of H3Africa will eventually lead to a skill set of African researchers who are able to independently conduct high quality genomics research. This was considered critical in ensuring that African researchers answer questions that is of relevance to their study populations.

> *In H3Africa, one critical element was building the capacity of the African research community so that the researchers would eventually have the required capacity, not only for the P.Is but also for the next generation of researchers. So you would have a cadre of researchers who would themselves be able to do the analysis and research to a high standard. So I think part of that inequities, recognising that it exist and starting to address it will be the right thing. So starting with the researchers and enabling them to collaborate in synergy with researchers was a good place to start because initially there wasn't enough expertise on the African continent. So I think this kind of*

twinning model which came out from the H3Africa was very important. So I think it is also important to focus on quality of capacity building. (Nxumalo)

Capacity building was also considered important in minimise exploitation as it would, in the future, enable African researchers to carry out their own independent research.

Capacity building is a big thing for us. And so for me, any policy that we build in Africa or that is an afro-centric policy just have to include that component. We have got the genetic material which the world is looking for. And it is not just a matter of just handing it out. We want to build resources so that we can in fact grow our local genomics expertise. (Kofi)

The different forms of capacity building listed in our conceptual framework came up in the interviews and they were similar to what we had also reported in a study on the benefits of genomics research in Africa (Munung et al., 2017).

The principle of FIHJ also requires that genomics research and biobanking consortia in Africa build capacity for the translation and uptake of genomics research findings. One way of doing this is through building capacity for genomics medicine and public literacy in genomics. In the document analysis, I showed that public engagement is listed as a component of H3Africa's capacity building plan. In the interviews this also emerged as a key area that will benefit from capacity building. Interviewees thought that was important for a couple of reasons, including: enabling study populations to comprehend research procedures and processes; empowering communities to take part in decision-making in genomics research and biobanking; a well as facilitating uptake of genomics medicine in Africa.

When we first formulated this in 2011, we realised that genomics in general, is not well known in the country… And our little experience at that time showed that investing in educating people before you started the study, was probably the right thing to do. We endeavoured to fill the gap so that it does not create a lot of problems for us as we carried out our research. So we had a multi-prong approach. We targeted the community in general, not just the community with Disease AA but the Country X community in general. We developed communication tools that you probably know about. And they were widely distributed, not just in Country X but across the continent as well. That opened up a dialogue, so you started to hear of all of these issues being discussed on radio…it opened up a social dialogue around genomics. (Ola)

In terms of capacity building in genomics medicine, we have, in a recent publication, reported the expectations of African researchers on capacity building in genomics medicine in Africa and the impact it could have on global health inequities (Munung et al., 2018). In this study, similar

views were also echoed and these are all in line with our framework's requirement for building capacity for genomics medicine in Africa.

6.3.3 Translation

The last of the three requirements of FIHJ is that global health research consortia should have a plan for the translation of research findings and to ensure that study populations have access to proven interventions.

The review of H3Africa documents suggests that caution should be applied when discussing translation as genomics research is still at the early stages in Africa. This was also echoed by some interviewees, but others stated that despite the need for caution in discussing translation, government funding agencies tend to prioritise research of which the outcomes are more likely to be translated to improved healthcare for local populations.

> *Sometimes improving health actually takes longer…. The translation is really interesting, so I think it depends on the scheme which you are funding in, but I think in its narrower sense there has been a focus, and there is more of a focus, especially from government funders, on translation outcomes or outcome-focussed research. (Nxumalo)*

Given the current context of genomics research, whereby the translation of research findings to clinical interventions or policy may be long term, a closer alternative to provision of post-trial benefits is the feedback of research results (generic and individual findings). Generally, interviewees felt that the feedback of individual genetic findings as well as general research outcomes should be mandatory. The suggestion to incorporate the feedback of genetic findings was always followed by an acknowledgement of the challenges and required capacity needed to return results of genomics research to study participants or populations in Africa. Firstly, in the context of research, it is not clear who has the obligation to take up the responsibility, given that researchers are not necessarily physicians and may not have the capacity to make clinical decisions based on a genetic test that was done as part of research. Secondly, there are a limited number of genetic counsellors to deliver test results and provide the required services. Thirdly, it is unclear what is expected of researchers in cases where the results are not "actionable". However, interviewees were of the opinion that sharing generalised research findings with study populations or individual test results with participants is important. Arguments for this were based on the principle of reciprocity.

> *It [feedback of study findings] is a very difficult issue and the problem is that often the data that the researchers have is not clear enough; it may just be raw research. But if you do find something that could be lifesaving, for example, then I think that the idea that there is an obligation to feedback*

information gets more force. And I think many people take that view. For example, the recent guidelines that were issued by the International Council of Medical Sciences, said there is an ongoing consensus that at least some information should be sent back. Then we have got the question of whose obligation is it, because researchers are not necessarily people's doctors… There is a shortage of genetic counsellors in Africa as in many other parts of the world. But I think there is a growing feeling that as an important part of reciprocity, that somebody has the obligation to feedback information that could be of benefit to research participants. (Kinela)

I did not engage researchers on the details of implementing the feedback of genetics findings in practice, as that would have been above the scope of this study. However, in a previous study, we had reported that limited capacity for the feedback of individual genetic test results, could be addressed through incorporating the training of medical geneticist and genetic counsellors as part of ongoing capacity building activities for genomics research in Africa (Munung et al., 2017, Munung et al., 2018). H3Africa has also developed a decision tree for the feedback of individual genetic test findings in H3Africa projects[22]. The policy is to feedback results only in cases where all of the following apply: the finding is actionable; there is consent for feedback of findings or these is the possibility to re-contact the participant; the test results have been verified by a certified laboratory or alternative genotyping test; and there are genetic counselling services or other healthcare providers within the project who can provide genetic counselling.

From the interviews and document analysis, it is obvious that a translational pathway for genomics research will require a multidimensional approach that goes beyond the availability of proven interventions such as diagnostics and therapies, to include: genetic counselling, health behaviour, and health economics. These different dimensions would have to be taken into consideration when developing a translational plan and building capacity for genomics medicine in Africa. This supports our governance framework requirements for FIHJ.

6.4 Reciprocity

The principles of solidarity and reciprocity are tightly linked and it was common for interviewees to use the terms interchangeably, as seen in some of the quotes above (Section 6.2 Solidarity). Solidarity-based reciprocity is about achieving a symmetrical relationship between the giver and the receiver and therefore generates an expectation by the giver to receive something in return (Tosam et al., 2017). For interviewees who were familiar with *Ubuntu*, this reciprocal relationship is necessary for equitable research collaborations in Africa. For instance, when one interviewee

[22] https://h3africa.org/wp-content/uploads/2018/05/H3%20decision%20tree%20final_print_3%20(1).pdf Accessed 27 January 2019

was asked what they considered a key guiding principle for governance of genomics research and biobanking in Africa, they responded that it will be reciprocity.

> *…reciprocity-This is seen in various cultures, where people are accustomed to returning favours done to them in equal measure" (Eyadema)*

To further highlight the need for symmetrical and reciprocal relationships, another interviewee mentioned that African researchers and other stakeholders should not lose sight of the purposes of genomics studies in Africa and the reasons why study populations provided samples and data, which is because they hope that the research will either be of benefit to them, to their communities or to the world at large. *Ubuntu* puts an obligation on stakeholders to ensure that the outcomes of genomics studies are made available and accessible to study populations in Africa and that they benefit from their participation in these studies. This justifies the need for benefit sharing arrangements in genomics research and biobanking in Africa.

> *Personalised medicine is one of the outcomes of very advanced genomics studies. But how many people, even if it becomes the future of medicine, how many of us Africans would actually afford that? Or even will our public health systems be available to afford that? So, while I really like the Ubuntu philosophy, but there is also that other aspect of the fact that we are living in a very capitalistic free market economy and we also need to negotiate appropriately for benefits and I think that is where the fair benefits arrangements come in. (Wanyika)*

In our governance framework, the principle of reciprocity could be operationalised in terms of having benefit sharing arrangements at the project level or at the level of the consortium. This may include: health development projects; capacity building; feedback of research results; public education in genomics and biobanking; access to genomic medicine interventions; and recognising the contribution of African researchers who were involved in the generation of the primary data. Just as in the analysis of H3Africa documents, reciprocity was discussed in the interviews in two major ways, namely benefits to study communities and benefits to H3Africa researchers. In terms of benefits to study communities, some interviewees suggested that it was important for genomics research consortia to articulate benefit sharing arrangements, as it is one way of recognising the contributions of research participants and study populations.

> *Do we have some sort of a reward system that recognises the communities for making available those bio-specimens? How will we see it in practice? Will it be in terms of monetary gains, is it in sharing of intellectual property downstream? I think there must be a way to recognise where the bio-specimens came from and by extension where the data came from. (Kofi)*

Some of the interviewees felt that having benefit sharing arrangements not only recognises the contributions of the community but are also an indication that study communities are not only used as an ends to a means. It is also shows respect for study communities and participants.

> *Once you have collected data from an area it does not mean that you forget about them, but you also even have to think about those people when it comes to sharing the benefits from the particular studies. So if you look at that in itself, it also resonates well with Ubuntu, where we are saying we do not want to exploit people, but we want to respect people and view them as complete beings, view them as part of us, and in that way we are then saying we need to share those benefits with them. (Chishala)*

A key question therefore is: what are the benefits of genomics research and biobanking that could be shared with study communities? I had suggested in the Framework that benefits could take the form of health development projects, capacity building, feedback of research results, public education in genomics; and access to genomic medicine interventions. Suggestions from interviews included the return of study findings, sharing of profits and the availability of proven interventions.

> *Well there can be a direct benefit of the research: return of results, therapeutic products, vaccines, kits all sold back at discount or made available for free. Then whatever proportion of your profits can be shared with the community, but there is no guarantee what kind of profit you are going to make (Sankara)*

Some of these benefits can only be made available if there is a translation plan by the consortium. This could be at the project or consortium level. Given that genomics is a basic science and that it make take time for the research findings to be translated to policy of clinical interventions, some of the interviewees felt that the return of study results (individual and generic) was therefore a direct benefit to study communities and participants.

> *I definitely think that there need to be a clause in there where we as researchers describe to the participants that information would be relayed back to them. And I think sometimes we find that people use the argument that do the public want to know the details? But I think it is not right. And we should share to the level that people can comprehend…. I think that also shows respect and it might be much easier for people in the future to relate to what you want them to do and then by extension you might have more participants in future etc. (Kofi)*

For some interviewees, knowledge is important and there should be a commitment by researchers to provide study communities with information emanating from their studies.

> *The benefits of research may not be tangible, and it may not even be a cure down the line although that may be hoped for, but knowledge itself is an important good which can be shared and also the benefit of building capacity in the places where research is done. (Kinela)*

Capacity building is another form of benefits that was suggested in the conceptual framework and this was echoed by our interviewees. In Section 6.3.2 (Capacity Building), I presented the benefits of research capacity building and stated that the limited capacity for genomics research and genomics medicine in Africa could widen global health inequities.

Overall, the interview data shows support for the principle of reciprocity. It also shows that a key way of actualising the principle of reciprocity was in the form of identifying appropriate benefits and having benefit sharing arrangements. Possible benefits that emerged from the interviews include: the feedback of results (both generic and individual genetic test results), research capacity building and access to proven interventions that may arise from these studies. Previous work in our group has detailed possible benefits and benefit sharing arrangements for genomics research and biobanking in Africa (Munung, 2016) and all these are in line with the proposed Framework.

6.5 Transparency

The Framework's principle on transparency demands that genomics research and biobanking consortia should ensure that institutional and decision-making processes are open, accessible and comprehensible to all stakeholders. It also requires the free flow of information amongst stakeholders. In the interviewees, transparency was seen as a core principle for the governance of genomics research and biobanking in Africa. Interviewees suggested different ways by which transparency could be promoted including: informing communities on the activities of the consortium; and making available information on the use of samples and data. They also described that transparency has the advantage of promoting trust between stakeholders.

> *I think one of the best ways of ensuring accountability and transparency is to make your guidelines and principles open on how you do things… I think one of the most important in accountability, which also contributes to transparency, is adequate documentation. So adequate documentation, traceability and those kind of things, those small practices, will make people, have trust in the system. (Wanyika)*

Some interviewees also suggested that transparency on the use of resources, particularly samples and data. There should be some documentation showing how resources have been used and/or equitably shared. This could for example be through: having reports on persons who have

accessed datasets from H3Africa projects; and the use of a biobank catalogue to document sample sharing.

> *I like this notion of a biobank catalogue. We have seen it in the H3Africa project. I saw it last year with another project where a summary information for each of the biobanks is captured somewhere, say on a website, and linked to that information, is information about what happened to the samples. And so that will be a place you can go to, to have a look and it could also be easy may be technically just to send out an alert also saying the samples are being used by this people out there. (Kofi)*

It was also suggested that stakeholder engagement could be one way of promoting transparency. The purpose of such an engagement is to inform the different stakeholders about the activities of the consortium and how it is achieving its goals. Again, the advantage of this approach is that it could build trust between the different stakeholders.

> *It is important to make effort and to provide information that is accessible to the people that are donating to ensure that transparency is respected and so the people know what is going to be done with their material and far as one is able to get the message across (Diarra)*

There was particular emphasis on ensuring that study communities and research participants are provided with adequate information on project. The reason for this emphasis could be that, compared to the other stakeholder groups, this group has been left out of many activities. It could also be seen as a way of respect for study communities as has earlier been described (See 6.1 Shared Sovereignty and 6.4 Reciprocity). The idea of the "right to know" was used to argue for this position.

> *Because I think they have a right to know. They have a right to know what the researchers are carrying out. What they are looking for. They may not be directly involved but it will be good that they should be aware of what the program involves. (Makena)*

Lastly, there is need for transparency in decision-making. This was usually discussed in light of the activities of the DBAC and there was the suggestion that genomics research and biobanking consortia should design protocols for documenting decision-making processes, including how decisions would be made and who would be involved in the process. This may involve the use of standard operating procedures.

> *Like in other scientific committees they need standard operating procedures which is developed in a very careful manner, in a thoughtful manner. I would*

> *suggest standard operating procedures on how to make decisions, how to approve studies, who to involve, will there be any monitoring. They need to discuss their responsibilities and at the same time also come out with standard procedures on how to execute those functions. (Lumusi)*

It was suggested that good communication practices on decision-making and use of resources as well as and inclusive processes were important in promoting transparency.

> *A bad collaboration is where parties are not communicating, are not disclosing intentions and activities at the right time, at the right manner. Where there are more than two groups, some groups may feel left out and they are not privy of what is going on. And then of course, abuse of resources or dishonest disclosure. (Sanyu)*

These different propositions support the Framework's recommendation for transparency in decision-making and the use of resources. In the framework, I had proposed that a consortium should make publicly available, the processes by which decisions are made. The idea of a standard operating procedure maybe one practical way of implementing the principle.

6.6 Shared Resources

One of the key requirements for equity oriented global health research is that resources should be shared such that resources received by each partner are in proportion to their needs. Also and that LMIC partner should ideally receive a majority of the resources. The Frameworks principle on shared resources requires that a majority of the research resources should be controlled by African researchers and research institutions, unless doing so would mean that the research does not get done (e.g. because of funding criteria) This is because inequalities in resources between LMICs and HICs involved in global health research consortia tend to confer more benefit to HIC partners and have a tremendous impact on overall decision-making. In Table 8 (chapter 5, Shared resources), I listed the different resources in genomics research and biobanking in Africa including: data, samples, human resources, infrastructure, IP and financial resources.

A requirement of H3Africa funding is that at least 51% of project funds should be spent in institutions in Africa. Equally, all H3Africa projects must be led by African researchers. The reason being that these allows for African partners to have more control of research resources. It also minimises power imbalances, in terms of resources, between researchers in Africa and HICs. A situation which has often put African researchers at risk of exploitation. In addition, the primary funding awards were made to African institutions who could then distribute funds to project partners, including collaborators based in HICs. Interviewees felt that this worked well in

minimising fears of exploitation and that other global health research consortia in Africa should emulate the H3Africa model.

> *My understanding of why that worked is specifically because the call was very clear that there has to be an African leader. And the way it was structured, the African PI was in charge of everything. Essentially everything had to be passed through the PI. So that is where I think it avoided a lot of problems that would have been caused by people feeling they are being undermined because they are not trained in genomics or people feel they are not up to scratch and all of that.(Ola)*

Interviewees also mentioned resources that were similar to those reported in the review of H3Africa document, including: samples, data, financial resources, human resources, research infrastructure, publication, IPs and patents. The Framework required that samples and data be made widely available, for solidarity based reasons, but that this should be done in such a way that recognises global inequities in health and research. In Section 6.3.1, I presented interviewees' preference for data and samples to be used for research that has a good probability of improving the health of populations in Africa and in reducing global health inequities. Interviewees also stated that samples and data are a key resource and should be shared such a way that allows African researchers to make maximum use of their datasets. This was mainly because of limited research capacity in Africa and past experiences of exploitation. In terms of addressing concerns of research inequities, one way this has worked out in H3Africa is to have an embargo period which allows African researchers to analyse and publish their data before it is shared.

> *I certainly do agree with the principle [publication embargo period] because Africa has been exploited over many years and I think that it is fair to allow people who have generated this data, but may not count as the most prominent researchers yet on the planet, to give them an opportunity to analyse that data and to draw whatever benefits they can in order to be able to advance their own research activities. If Africa had not been exploited for all these decades and they had not been such a discrimination which has resulted in this huge difference in capacity between our continents and for example Europe or North America, then I would say that embargo is not justified. (Diarra)*

Another point that emerged from the interviews, in relation to research resources was ownership of samples and data. In the framework, the shared resources principle requires that the primary research institutions in Africa serves as custodians of samples and data. In the interviews, there was a perception that ownership of samples and data is quite controversial, with some

interviewees suggesting that ownership claims on samples should be avoided in preference for custodianship, while data ownership should rest with the researchers who generated the data.

> *So my view of ownership of [bio]material is that normally the entity that is keeping the [bio]material, there is nothing like absolute ownership but the entity that is keeping the material should hold this in in trust on behalf of the material providers. So that is with respect to material. But ownership of the data that is generated out of the material should be vested on those who have made an intellectual contribution to that data (Wanyika)*

Issues of ownership rights have downstream implications for intellectual property and patents of innovations that may arise from the use of data. It was suggested in the interviews that IP rights for innovations should be retained by research institutions rather than individual researchers. The expectation was that institutions would ensure that royalties are provided to the innovators.

> *I am comfortable with the idea that the institution should own the IP. That doesn't mean that it can't be utilised by people even within the university through licensing for example, of a patent. Because those benefits then flow back to the university and also to inventors. (Diara)*

Given that data are generated from samples, it is confusing if someone was to have custodianship of samples while data ownership is assigned to a different entity or individual. I had suggested in the framework that data ownership should be assigned to the institutions. I will keep this recommendation. This is because if interviewees expect IPs to be owned by research institutions, then by default, they would need to have some "ownership" claims over the data. However, issues of patents, ownership of data and IPs will benefit from future studies.

6.7 Shared Responsibility

Shared responsibility is a core principle in our governance framework. Questions to interviewees on shared responsibility mainly explored the responsibility of stakeholder groups in terms of the equity-oriented activities, such as: FIHJ (selecting research target, capacity building and translation); shared sovereignty; and reciprocity. The responses were similar to the requirements of our framework, which is that stakeholders be assigned responsibilities based on the function that they typically assume. In the interviews, the responsibility for capacity building was assigned to funders and national governments; the return of results to African researchers and healthcare workers; and community engagement to African researchers. The interview data also suggested that funders have the responsibility of ensuring that genomics research in Africa aligns with local health needs. This was because they believed funders had the required financial resources and can therefore promote equity oriented research by directing research funding to the health

needs of the study population. This was not to say that funders should dictate the research agenda. Rather, it was suggested that research priority setting should be guided by epidemiological parameters.

> *There is usually the problem that the funding countries or the funders might actually dictate what issues to focus on. But what we are saying is, researchers need to focus on diseases that are affecting the majority of populations across Africa. (Chishala)*

This also suggests that African researchers have a critical role to play vis-à-vis the funders in identifying and selecting research priorities for genomics research and biobanking in Africa. African Researchers were assigned this responsibility because they assume leadership roles (P.Is) in projects and are therefore expected to conduct research that is of relevance to their communities.

> *They [African researchers] have a responsibility of leadership. The need to be those who plan the research with regards to the priorities of their countries. They have to convince the funders that the money should be used for research that is important for their countries and not the priority of the funder. The problem with African researchers is that as soon as someone is ready to pay the say yes....They have to try to convince the funders, the policy makers and the western partners that this is what we want to do and do not let us waste our time on something else because this is the priority of our country. (Makena)*

From the quote above, it can be said that funders and African researchers have the responsibility of ensuring that genomics studies aligned to local research and health priorities. These views are similar to our frameworks requirements for shared responsibility.

The responsibility for building research capacity lies with the nation state. But justice requires that when nation states are unable to do build their research capacity, global health actors should support them to do so. This has been the case for genomics research and biobanking in Africa. The interview data however revealed that a heavy reliance on funders is not sustainable and that African governments have to take up their primary responsibility of building capacity for health research in their respective countries. To show the importance of government involvement in research capacity building, one interviewee said that in countries where there has been government commitment, genomics research projects have thrived.

> *I do not think the funders have the responsibility to completely redress all the inequities. I think local governments have the responsibility to up their research spending and build some of the infrastructure that needs to sit*

> *underneath some of these initiatives. The ones that flourish in H3Africa, I still think, are the ones for which local government was involved and there was pre-existing infrastructure. So I think it is a mixed model; I think for funders, if you are going to fund this type of initiative then capacity development is part of it, and you have to acknowledge it. But that cannot solely rest with the funders, some responsibility has to be taken by local government, and that is a tough thing to ask, but some African governments do see the value in doing it. (Nxumalo)*

In terms of benefit sharing, whilst there are challenges associated with the return of research results, the H3Africa policy for the feedback of genetic test results assigns the responsibility of return of incidental findings to principal investigators. Interviewees who mentioned the return of study results as a primary benefit equally saw it a sign of respect for study communities and a way of building trust between researchers and study communities. An additional suggestion was made for an independent body to be responsible for benefit sharing arrangements. This is similar to what we had previously reported in a study that interviewed African genomics researchers (Munung, 2016). The current study however suggested that this responsibility should be extended to African researchers, funders, and secondary users of data/samples from H3Africa projects

> *I think in as much as the decisions around what benefit sharing should look like need to be taken by the three groups that are mentioned….there should be an oversight group or an oversight body which, again, is constituted of the three groups that we have mentioned and who would then do the knots and bolts. I think it will ultimately have to come from either the state or it would have to come from the private sector like a private company that has been employed specifically for this purpose (Diara)*

Responsibilities should be allocated based on the functional requirement principle, that is, responsibilities should be assigned based on the function that a stakeholder group will typically assume. The interviews suggest that the responsibilities assigned to funders and to primary researchers are in line with our framework recommendations. However, the introduction of an independent body for benefit sharing arrangements will need to be considered when revising the framework.

6.8 Mutual Trust

In developing the framework, I mentioned that trust is a necessary precondition of solidarity and that it is difficult to imagine solidarity based relationships that are void of trust. I then proposed that the principle of trust could be promoted in genomics research and biobanking consortia through recognising the interdependence of all stakeholders (solidarity) and also acknowledging

the contributions that the different stakeholder groups are making towards the overall success of the success of the project. This could take the form of public engagement activities and recognition of the contributions of African researchers (e.g. acknowledgement in publications and conference papers). Interviewees identified different relationship in genomics research and biobanking where the principle of trust is key. This includes: relationships between HIC and African researchers/institutions and relationships between researchers and research participants or study communities. Trust between African and HIC researchers could be built through respecting collaborators and ensuring that the voices of all partners are given equal regard. Respect also emerged in the interviews as a key value that is important in fostering trust between the different stakeholder groups.

> *So if we are looking at trust between the researchers, that is, between the researchers from Africa and those from the north, it is very important for them to maintain that trust. Trust can actually come out through respect for each other, if the researchers from the north respect the researchers from Africa and then those from Africa respect those from the north, then they actually know that they will be deciding on issues together.(Chisala)*

It was also suggested that a broader approach to building trust is through research integrity mechanisms. According to one interviewee, current research malpractices in global health research have led to the breakdown of trust between collaborators. This includes failing to give credit to collaborators in research outputs such as publications. To remedy this situation, it was suggested that research institutions should develop policies on research integrity that cover some of these salient issues.

> *But there are also issues within a research project; people taking credit for work that has been done by other people, and this is all a huge international problem now, in terms of what is called research integrity. For example people publishing fake publications or stealing someone else's intellectual property; I think research integrity is the key here….. So I think it would be good to have some consultation with every consortium about the kinds of mechanisms that promote research integrity in Africa. (Kinela)*

Generally, it was felt that trust between researchers in Africa and researchers in HICs was not straightforward and would take time to build mainly because of historical experiences of exploitation of African researchers. Based on the observation that African researchers are more likely to share data with researchers with whom they have an established and trusted research collaboration (Carr and Littler, 2015, Bull et al., 2015), I had proposed in the framework that efforts should be made to support collaborations for which there is a long term plan for collaboration. As discussed in Section 6.2 (solidarity), building trust can take time and tends to

be stronger between persons who share the same values. This supports the need for long term collaborations. Interviewees also described that tools such as memorandums of understanding or mutually agreed terms could play an important role in promoting or maintaining trust.

> *Trust between primary PI's and the international collaborators is a totally different story, I do not think it is easy, because historically it is not there, there is no historical precedent for that. And trust is something that you build up over time……I believe you need a contract to support trust between PI's and their collaborators, you cannot base it on good faith (Sankara)*

On the other hand, trust between researchers and research communities could be built or sustained through respect for study communities, open communication with study participants or communities and engaging study communities as partners in research rather than sample donors only. As reported above, and in previous sections, having respect for study communities requires informing them of research procedures and outcomes as they have the right to know how their samples and data are being used to improve the health of populations in their communities and globally. It will also requires involving them, like other stakeholder groups, in decision-making.

> *Trust also has to do with dissemination of information; trust also has to do with looking or viewing communities not as means to an end but also as ends in themselves. Here, what we are saying is viewing our communities not simply as a source of raw materials for research, but as a partner in the research process. That kind of respect actually brings about trust between the research communities and the researchers. But there is also need for open communication lines between those two groups… I have seen some groups who have been coming up with stakeholder engagement plans which clearly detail the various bits that are put in place, to improve the relations between the research communities and the researchers. (Chishala)*

From the interview data, respect, accountability, shared decision-making and transparency are necessary factors for building trust between stakeholders in genomics research and biobanking in Africa and interviewees often discussed these principles together. The suggestions conform to our framework requirements for the principle of trust which include: recognising the contributions of all stakeholders; stakeholder engagement; and transparency on samples and data use, as well as inclusive decision-making processes.

6.9 Mutual Collective Accountability (MCA)

Mutual collective accountability (MCA) is about ensuring that stakeholders are accountable to one another. Our framework requires that genomics research and biobanking consortia in Africa

establish ways for ensuring: that shared sovereignty is achieved; that resources are being used towards promoting health justice; and that all actors are performing their assigned roles and responsibilities. The MCA principle requires that this be done through setting standards for decision-making processes and identifying indicators and benchmarks for success. Interviewees generally considered accountability to be a key principle for the governance of genomics and biobanking in Africa. However, many interviewees felt that the implementation of MCA will be relatively difficult because of challenges with identifying which stakeholder group should be accountable to the other and at what phase of the research project. This is because MCA is about stakeholders voluntarily agreeing to be accountable to each other, therefore penalties are unlikely. Nonetheless, some interviewees suggested that accountability mechanisms within the consortium need to be developed and that this is the responsibility of the funders.

> *The problem with accountability is who should be held accountable, who are they accountable to? I think you need to figure out who the person is going to be accountable to and at what level. Because if we are saying that it is the ERCs [RECs] that are accountable, they have no enforcement procedures. Yes, they can decide that they're not going to issue a renewal in the year the progress report is sent in. But that never actually happens. So who potentially can have the most oversight? It is probably the funders. (Palesa)*

For other interviewees, the challenge of implementing MCA could be overcome through assigning the responsibility of accountability to an independent agency.

> *There should be an agency who would take responsibilities when something needs to be accounted for. So such an agency needs to be identified. Like the researchers would need to be accountable, ethics committees needs to be accountable and experts like the international collaborators need to be accountable to different stakeholders…. I think it is a shared responsibility between the parties in the collaboration. (Lumusi)*

However, the consortium will have to first define the responsibilities of each stakeholder group, without which it will be almost impossible to hold any stakeholder accountable. This is in line with the shared responsibility requirement. In the document analysis, I demonstrated that besides annual reports submitted to funders by principal investigators, there was an emphasis for accountability mechanisms for sample and data sharing. The document analysis also showed that secondary users of data are accountable to the DBAC, whilst the DBAC is accountable to the primary ethics committees and to the steering committee; and researchers are accountable to RECs and to study communities. These different forms of accountability also emerged from the interviews.

one has to take responsibility for the material that one is analysing and for the data that is generated and it needs to be protected and the researchers that are obtaining this material have a duty to ensure that the data that comes from this is fed back in a meaningful way. So this covers a broad spectrum all the way from interacting with the community after the study to directly working with the communities to providing them with information which again requires a tremendous amount of skills because it is difficult to give this information back without making people anxious and fearful. (Diarra)

Different layers of MCA came up in the interviews ranging from: accountability by primary data collectors to the ethics committees that approved the primary studies; accountability by primary researchers to study communities; accountability to funders by primary researchers; the DBAC to the entire consortium. Interviewees also suggested a number of ways by which accountability might be actualised was through monitoring of samples and data use and this responsibility was assigned to the DBAC and biobanks.

I don't know if it is the DBAC who should make a report stating these are the request we received, this is what we approved to share this year and for this reason or there needs to be a body that that checks what the DBAC is doing. There should be an activity report from the biobank. There is a need to know what has been done with the samples and data and also as a proof of concept. Because also this is something quite new, to show that so far it has been useful to store the samples in a regional biobank in an African biobank and that so far it has been useful and has increased the number of publications from the funding, that there are African scientist who are ready to speed up research activities (Makena)

Another area where MCA is expected is in decision-making. Our governance framework requires that genomics research and biobanking consortia in Africa should monitor and ensure that decision-making processes are inclusive. This form of accountability was not found in the document analysis. In the interviews, it was suggested that it could be done through developing mechanisms for stakeholder engagement.

I think there are several ways of promoting accountability and transparency, Part of it [accountability] would also be to encourage all the groups to come up with clear stakeholder engagement plans that clearly describe how information is going to be disseminated to the various stakeholders, that clearly show the various stakeholders that are H3Africa partners working with, so as to improve the relations and also transparency (Chishala)

Responses for MCA are in line with our framework's principle of MCA, but for the suggestion that an independent committee should monitor and evaluate if a consortium is achieving its equity oriented goals. The document analysis revealed that the IEC has the role of doing a peer review of the consortium's activities. This will be considered as an addition to our framework.

6.10 Chapter Summary

In this chapter, I have presented the analysis of the interview data and compared the data with the principles in our governance framework for genomics research and biobanking in Africa. I also described points of divergence between the proposed Framework and the empirical data. Overall, the empirical data largely supports the normative theories and recommendations made in our principles-based governance framework, but for minor differences in framework requirements, and an emphasis on the importance of the principle of respect. In the next chapter, I will discuss these differences and indicate possible areas of revision.

Chapter 7: Framework Revision and Application to Justice-related ELSIs in Genomics Research and Biobanking in Africa

In the last two chapters, I reported on the results of the empirical work that was conducted as part of the overall study. This involved thematic analysis of H3Africa governance-related and one-one-in-depth interviews with different stakeholders in the H3Africa consortium. The data was analysed against the principles in the proposed Framework (Chapter 3), and the results showed a broad support for the Framework's principles and recommendations. In this chapter, I report on the points of divergence between the empirical data and the principles promoted in our framework. I also presented the revisions that will be made to the framework.

7.1 Conceptual Governance Framework versus Empirical Data

The aim of the empirical arm of this study was to test the principles in the proposed framework against existing governance policies of a genomics research consortia in Africa; and the expectations and experiences of different stakeholder groups. To do this, I used the reflective equilibrium approach. Reflective equilibrium requires using methods of scientific inquiry to test a normative conclusion or statement (Davies et al., 2015, De Vries and Van Leeuwen, 2010).

I probed two types of empirical data: H3Africa governance documents and in-depth interviews with H3Africa stakeholders. Where there were differences between the framework requirements and the empirical data, I checked if these differences were related to the practical implementation of the recommendations made in the principle itself was not considered an important driver for promoting justice and fairness in genomics research in Africa. Where the differences were more of concerns related to practical implementation, I checked the empirical data with existing literature to see if there was support for that particular view from other studies. If the literature showed support for the empirical data, the Framework was revised accordingly. The same applied where a new principle emerged from the empirical data. In which case, I equally checked if the new principle was related to any of the principles in the Framework. If that was not the case, and existing literature showed that the principle was important for promoting justice in global health research, it was then added it to the framework as a new principle.

Overall, the principles were broadly supported by the empirical data but for minor points of divergence, related to the recommendations on how the principles could be actualised. A new principle, mutual respect emerged from the scientific enquiry (mainly interviews).

7.1.1 Points of Divergence and proposed revisions

Points of divergence between the empirical data and our conceptual framework were identified for the following principles: shared sovereignty; furthering the ideals of health justice (FIHJ); shared responsibility and mutual collective accountability (MCA). A principle that emerged from the empirical data which was not part of our conceptual framework is mutual respect. I present these different points of divergence and the possible points for revision. In presenting the principle of mutual respect, I will provide supporting quotes from the data. This is because compared to the other principles, I had not previously presented the data on mutual respect. Following a discussion of each point of divergence, I will include text for a proposed revision of the framework.

7.1.1a Mutual Respect

Interviewees frequently mentioned that mutual respect between stakeholders was a necessary requirement for genomics research consortia. In the documents analysis (Section 5.1.3; Relevance), the best practice guidelines emphasises the need for respectful and harmonious relationships between stakeholders. In the interviews, reference was also made to the importance mutual respect as a principle that should guide interactions between stakeholders. Interviews also linked the principle of mutual respect, to other principles in our conceptual-based governance framework such as reciprocity, shared sovereignty and trust. For example, some interviewees where of the opinion that reciprocity-based activities such as benefit sharing are a sign of respect for study communities and an indication that study communities were not used as a means to an end. Other scholars have also demonstrated the interconnectedness of the principles of mutual respect, reciprocity and trust (Merson et al., 2015, Umoren et al., 2012).

Mutual respect is the feeling shared between two or more people, on the value or importance of something or someone. Ubuntu as about communitarianism and humanness, and at the centre of that humanness is reciprocity, which also demands that individuals respect one another because they need one another, irrespective of one's social class (Dolamo, 2014). A number of authors have argued that the principle of mutual respect is important in global health research collaborations (Hunt and Ridde, 2016, Tindana and de Vries, 2016, Moodley, 2017) and genomics research and biobanking. In the interviews, mutual respect between stakeholders was also considered a key principle that should be promoted in genomics research and biobanking in Africa. This suggestion was made mainly in reference to study communities and mutual respect between researchers in HICs and African researchers.

> *I think one fundamental principle is respect. Respecting the communities that actually provide the genomic data. Like the sources, the sample sources for instance. Those communities should be respected. (Wanyika)*

In societies that live by *Ubuntu*, mutual respect is seen as inherent in promoting human dignity, regardless of a person's social standing (Arthur et al., 2015, Mcunu, 2004). Similar views were echoed in the interviews.

> *So the issue of dignity, respect of the participants and the researchers and the issue of ensuring that exploitation is not repeated and that there is a fairness in the way in which the process is undertaken, that if there were any benefit to be derived from this, it is shared in a way which is equitable (Diarra)*

Overall, some interviewees were of the opinion that in a research collaboration where mutual respect exist, and where stakeholders and collaborators treat each other as moral equals, the chances of one group exploiting the other are likely to be minimised.

> *Ubuntu is that which separates human beings from animals, so understanding Ubuntu actually means you are understanding issues to do with personhood. Understanding Ubuntu is about understanding how to respect someone…So if you look at that in itself it also resonates well with Ubuntu, where we are saying we do not want to exploit people, but we want to respect people and view them as complete beings, view them as part of us, and in that way we are then saying we need to share those benefits with them. (Chishala)*

When interviewees talked about the principle of mutual respect, they mainly referred to mutual respect between researchers and study populations and between HIC researchers and African researchers. It was alluded that showing respect for study communities requires researchers to engage with study communities about research procedures and outcomes. It was also suggested that showing respect for study communities has the potential to build trust and to establish a good relationship that would facilitate future research. Some interviewees therefore thought that informing study populations on research progress and outcomes should be included in governance-related policies and that this responsibility should be assigned to African researchers.

> *I definitely think that there needs to be a clause in there where we as researchers describe to the participants that information would be relayed back to them. And I think sometimes we find that people use the argument that does the public want to know the details? But I think it is not right…….So I would be pushing for information. Once we get the data, it is to go through the channels through which the informed consent was obtained and then make available either a summary information via the nurse or staff member or the persons who were in contact with the community, to then get back to them and give them feedback. I think that also shows respect and it might be*

much easier for people in the future to relate to what you want them to do, and then by extension you might have more participants in future. (Kofi)

In terms of mutual respect between African researchers and HIC researchers, it was suggested that this would require that the voices of African researchers are taken into consideration during decision making processes, especially in decisions on how samples and data would be used. The emphasis on samples and data could be an indication that fears of exploitation of African scientists consolidate around these resources. Some interviewees argued that is disrespectful to be in a collaboration where the concerns of African researchers are not considered.

When I was talking about respect, at that moment I was actually talking about respect between the researchers from the richer countries and researchers from African countries. So here I mean as part of the collaboration the voices of African researchers should be heard, so it is not about researchers from the richer countries dictating what is supposed to be done as part of that collaboration. But we are saying that the researchers from Africa should also have their voices being heard and should also be able to suggest what can be done using the data. (Chishala)

It can be inferred from the quotes above that there is a link between mutual respect, reciprocity and shared sovereignty. Also, mutual respect was often talked of in terms of African communitarian values and its importance in upholding human dignity. I acknowledge the added value mutual respect brings to equitable global health research collaborations, as argued by the interviewees, and also how it links to reciprocity and trust. Given the emphasis on this principle and that it serves as a foundation for some of the other principles promoted by *Ubuntu*, I will revise the framework to include mutual respect as a key principle. It also shows that there is added value if genomics research and biobanking consortia in Africa are governed based on local values and norms. This is in line with the relevance requirement of shared sovereignty.

7.1.1b Framework revision

Mutual respect

Mutual respect is the feeling shared between two or more people, on the value or importance of something or someone. It is an integral part of an African communitarian worldview and involves respecting one another because we need one another, irrespective of differences in resources and social standing (Dolamo, 2014). Respect is also a value integral to promoting human dignity (Arthur et al., 2015, Mcunu, 2004).

- Genomics research and biobanking consortia in Africa should ensure that their policies, processes and procedures are in line with local values and norms.

- The voices of African stakeholders (researchers, policy makers and study communities) should be solicited and taken into consideration when designing polices for genomics research in Africa.

- Genomics researchers in Africa should inform study communities of the progress and outcome of studies in which they participated. This includes information on how samples and data have been used.

7.1.2 Shared Sovereignty

A second point of divergence between our framework and the empirical data, was for the principle of shared sovereignty, specifically the involvement of study populations in decision making. Shared sovereignty requires that all stakeholder groups who may be affected by a decision should be involved in decision-making (inclusiveness) and that decisions should be reached via consensus. Whilst the interview data showed broad support for including study populations in decision making, there was also the perception that it will be practically difficult to do so. This was primarily based on concerns of identifying representatives of study populations.

Despite expressed concerns on practicalities of including study populations in decision making, I will keep the principle in the framework. This is because the inclusion of research participants in the governance of global health research avoids an expert driven governance model that has in some instances led to great criticism and loss of trust in biobanking projects (Palsson, 2008). Also interviewees considered it important that participants should be given a voice in decision making, a view that has also been recently echoed by some bioethics researchers (Juengst and Meslin, 2019). H3Africa governance policies also suggest that public engagement is important for transparency and building trust. Considering the apparent consensus on the importance of the principle, the only problem appears to be with its practical implementation. In the literature, there are suggestions on how research participants or communities could be involved in the governance of genomics research and biobanking (Avard et al., 2009, Dry et al., 2017, McCarty et al., 2011, O'Doherty et al., 2012). These include: the use of surveys; public discourse; community engagement; focus group discussions; consultations and public meetings, all of which can be broadly categorised as public engagement activities. Some of these suggestions are consistent with the interview data on possible ways of including study populations. Future work on appropriate mechanisms for including study populations in decision making in of genomics research and biobanking consortia in Africa will be important. No changes will be made to the shared sovereignty section of the proposed framework.

7.1.3 Furthering the ideals of health justice (FIHJ)

The third point off divergence between our conceptual framework and the empirical data is the principle of furthering the ideals of health justice (FIHJ), specifically with regard to research priority setting. In the framework, I proposed that genomics research projects in Africa should focus on health conditions that are a major contributor to disease burden in Africa and for which genomics research is likely to yield maximum public health benefit. Our empirical data (both document analysis and interviews) are coherent with this recommendation. However, the empirical data suggests that priorities for genomics research and biobanking in Africa should be broadened to also include rare diseases (section 6.3.1). The reason being that the monogenetic nature of most rare diseases makes them good models for genomics studies in generally, but also because the rarity of these conditions often means that persons affected by them often struggle with the management of their conditions, from diagnosis to treatment because of limited investment in research on these diseases. Genomics could serve as a way of finding the underlying genetic causes of these diseases, assist in developing new diagnostics as well as lead to changes in medical care for patients with rare diseases. The framework will be modified to capture this suggestion.

7.1.3a Framework revision

Genomics research and biobanking consortia in Africa should, in addition to health conditions that are major contributor to the disease burden in Africa, also prioritise genomics studies on rare genetic conditions. This would allow for the development of diagnostics, rational drug design and for the development of very specific agents that would improve the health of worst-off populations with rare diseases, without which health inequities within the same population group will be worsened.

7.1.4 Shared Responsibility

The fourth principle where there was divergence between the framework's principles and the empirical data is the shared responsibility requirement for benefit sharing. I had assigned the responsibility for benefit sharing to researchers, research institutions and funders. The interview data suggests that in addition to funders and researchers, an independent body may be used to enforce the implementation of benefit sharing. This view has also been expressed by other genomics researchers in Munung et al (2016). Given the complexity of implementing benefit sharing mechanisms (Schroeder et al., 2005, Schulz-Baldes et al., 2007), an independent organisation familiar with the process may be best suited to carry out this role. This is line with the functional requirement principle (which forms the bases of the shared responsibility) that were stakeholders are unable to carry out their role, they may be supported to carry out their responsibility. This does not shift the responsibility of benefit sharing from researchers and

funders, rather it is to support implementation. I will add this recommendation to the revised framework.

7.1.4a Framework revision

Genomics research and biobanking consortia may use an independent organisation or entity as one approach to implementing benefit sharing arrangements. The role of this organisation should be defined by African researchers, funders, study populations and policy makers including how their responsibilities differ from those of other stakeholders who have benefit sharing responsibilities

7.1.5 Mutual collective accountability

The fifth and final point of divergence between our framework and the empirical data is with the principle of mutual collective accountability (MCA). MCA is a system of peer review whereby stakeholders are answerable to one another, and in some instances to an external body (Ruger, 2012b). The latter is only permissible when the roles and responsibilities of the different stakeholders are clearly defined (Ruger, 2013). The empirical data suggest that an external body may be required to implement MCA. The H3Africa document review for example, showed that this task is currently assigned to an independent expert committee, whilst the interview data suggests that it should be delegated to an independent organisation with no affiliation to the H3Africa consortium. I will include this suggestion in the framework. This is because in cases where accountability to an external body is required, the roles and responsibilities for stakeholders should be clearly defined. Our framework principle on shared responsibility requires that genomics research and biobanking consortia clearly identify the roles and responsibilities of all stakeholders who are involved in the project. Just like with the revision for shared responsibility, above, this is more about a change in implementation, rather than in principle.

7.1.5a Framework revision

Genomics research and biobanking consortia in Africa may use independent organisations to evaluate if the consortium is achieving its equity oriented goals. In which case the roles and responsibilities of all stakeholders as well as indicators for success should have been clearly defined by all stakeholders specifically, study populations and African researchers/institutions, as these stakeholder groups are most affected by inequities in genomics research in Africa.

7.2 Application of the Principles-based Governance framework to Justice-Related ELSIs in Genomics Research and Biobanking in Africa

In chapter 1, I presented the justice-related ELSIs in genomics research and biobanking in Africa (See section 1.1). I also mentioned that most of the justice-related ELSIs are shaped by data and

sample sharing practices that characterise population genomics research in Africa. Some of these ELSIs can be linked to the history of scientific imperialism or "extractive "biomedical research collaborations in Africa (Okwaro and Geissler, 2015, Tangwa, 2017, Parker and Kwiatkowski, 2016). The justice-related ELSIs in genomics research and biobanking in Africa which I described in chapter 1 include: exploitation of African populations; ownership of samples and data, access to samples and data, benefit sharing, intellectual property/patents. In Table 10 below, I present the different principles in our framework that may be used when addressing these different ELSIs.

Table 10: Link between principles and recommendations proposed in the governance framework and the justice-related ELSIs in genomics research and biobanking in Africa

Justice-related ELSI	Framework principles that address the ELSI	Examples of framework recommendations that help address the ELSI
Exploitation of African researchers and study populations	FIHJ Shared sovereignty Shared resources Mutual respect Solidarity Reciprocity Mutual trust MCA	Voices of all stakeholders should be included in decision making. Genomics research in Africa should prioritise the health needs of African populations. A greater proportion of the resources should be allocated to support capacity building of African researchers and research institutions. Where genomics research leads to new interventions, these interventions should be made available to study populations. The contributions of primary data producers should be acknowledged in publications and other outputs emanating from the use of samples and data.
Access to samples and data	Solidarity Shared resources MCA Shared sovereignty FIHJ Shared responsibility	Samples and data should be shared for use in research. However, sharing of samples and data should take into consideration the health needs of African populations who provided samples and by extension, data. Samples and data should be used to address health issues that are a major contributor to the disease burden in Africa. Research consortia should provide study populations, research ethics committees that reviewed the primary studies and African researchers with information on how samples and data have been used.

		Decision making on access to samples and data should involve all affected stakeholders Priority for access to samples and data should be given to research projects that either have a plan for collaborating with African researchers, addresses the health needs of populations in Africa or that that allocate resources towards capacity building in LMICs
Ownership of samples and data	Shared resources Solidarity Mutual trust	Research institutions involved in primary studies should serve as custodians for samples and data stored in biobanks and databases respectively
Benefit sharing	Solidarity Reciprocity FIHJ Mutual Trust Mutual respect Shared resources	In cases where an intervention is developed from the study, there should be mechanisms in place to ensure sustained access to the intervention Genomics research and biobanking consortia should carry out public engagement activities that aim at communicating project-related information, such as use of samples, research outcomes and study progress, to study populations Genomics research consortia should state what kind of benefits are likely to accrue to study communities because of their participation in studies
Intellectual Property and patents	FIHJ Shared resources	Researchers and research institutions that file patents or IP rights for innovations arising from the use of genomic datasets should disclose how they would ensure access to resulting products by populations in Africa Contributions of African researchers and research institutions should be recognised when filing patents or IP rights

7.3 Chapter Summary

I used the reflective equilibrium approach to test our framework's principles against current governance practices of genomics research as well as the governance expectations of different stakeholders in genomics research and biobanking in Africa. Our goal was to have a framework the principles and recommendations of which can be considered binding for all rational agents and are also not too abstract or far removed from reality so that they can usefully inform practice (Davies et al., 2015). In this chapter, I presented the points of divergence between our governance framework and the empirical data and proposed the introduction of a new principle (mutual respect) and revisions to the governance framework. I ended the chapter with a presentation of the different principles in our governance framework that could be appealed to when addressing the different justice-related ELSIs in genomics research and biobanking in Africa.

In the final chapter of this thesis, I will briefly discuss the outcome of our study and make recommendations for future research.

Chapter 8: Discussion, Future Research and Conclusion

Recent years have seen an increase in population genomics studies in Africa, largely fuelled by fears of a possible genomics divide that would in turn widen global health inequities. (Gurdasani et al., 2015, H3Africa Consortium, 2014, Singer and Daar, 2001a). The success of these population genomics studies depends on: a well-coordinated network of collaborative studies; the establishment of biobanks; and the sharing of samples and data with other researchers. However, data and sample sharing raise a number of ethical, legal and social issues (ELSIs) that will need to be addressed by genomics research consortia in Africa. Some of these ELSIs focus on individual-level issues (micro-level justice), others are more concerned with broader societal issues (macro-level justice). This thesis sought to propose a governance mechanism that could be used to address these macro-level justice concerns in genomics research in Africa. This is important as there is a near absence of regulatory support that could be used as a backbone to address justice-related ELSI raised by genomics research and biobanking in Africa (de Vries et al., 2017). Also, the absence of harmonised regulations for the export of samples and data in Africa means that there are differences in country-level regulation on how specific ELSIs could be addressed. The development of governance mechanisms that are broad enough to address these ELSIs could be an approach to filling this gap in regulation (Chen and Pang, 2015, de Vries et al., 2017, Parker and Kwiatkowski, 2016). Such governance mechanisms will have to be based on principles that could foster sound ethical research in Africa (de Vries et al., 2017) and which are reflective of African cultural values (Staunton and Moodley, 2013). In this thesis, I used the normative bioethics oriented approach (NPOB) to develop a principles-based governance framework for genomics research and biobanking in Africa. The Framework is informed by: two different theories of global health justice and governance and the African moral theory of *Ubuntu.* Its principles were identified using a convergence approach. Its recommendations were further tested using the reflective equilibrium approach, an empirical bioethics method.

8.1 Summary of Study and Discussion

In this thesis, I set out to develop a governance mechanism that could address the justice-related ELSIs in genomics research and biobanking in Africa. The specific objectives were to:

1. Identify principles, values and norms that can promote justice and fairness in genomics research and biobanking in Africa;
2. Propose a principles-based governance framework for genomics research and biobanking in Africa that links its policies to the promotion of justice;
3. Investigate how the governance of current day genomics research and biobanking projects in Africa have considered concerns of justice and fairness;

4. Explore the views of key stakeholders on fair and just governance mechanisms for genomics research and biobanking in Africa.

I started with a description of the justice-related ELSIs in genomic research and biobanking in Africa. These were mainly issues related to: access to samples and data; benefit sharing; ownership of samples and data; intellectual property; and the exploitation of African researchers and study populations. I argued that these justice-related ELSIs could be best addressed through governance. Governance is about principles, values, norms, rules and decision making processes that guide the activities and expectations of actors involved in a specific activity (Hufty, 2011, UNDP, 1997). Whilst governance may be principles-based or rules-based (Arjoon, 2006), I opted to develop a principles-based governance framework.. The reason being that principles-based governance is broader in scope and has more latitude and flexibility compared to rules-based governance. Therefore the framework will likely appeal to the broad range of stakeholders involved in genomics research and biobanking in Africa.

In order to identify principles that may guide the governance of genomics research and biobanking in Africa, I turned to two theories of global health justice and governance as well as the African moral theory of *Ubuntu*. The two theories of global health justice were: shared health governance (SHG) and global governance of health (GGH). I selected these theories because they link global health research to the promotion of justice. Also, they provide guidance for the governance of global health programs and argue that health research should aim to addressing global health inequities. *Ubuntu*, on the other hand, has informed governance in many African settings. It is also considered the way of life of African people. Using the convergence approach, I did a conceptual and normative analysis of SHG, GGH and *Ubuntu* to identify principles that could inform the governance of genomics research and biobanking in Africa. This required identifying principles and/or values that were common in SHG, GGH and *Ubuntu*. I then used these principles to develop a framework for the governance of genomics research and biobanking in Africa. The following principles were identified from the conceptual and normative analysis using the convergence approach: shared sovereignty, transparency, shared resources, shared responsibility, mutual trust and mutual collective accountability (MCA) (Table 2). Principles which were not promoted by all three governance theories, but which were included in the framework include: Furthering the ideals of health justice (FIHJ), solidarity and reciprocity. FIHJ is promoted by SHG and GGH and not directly by *Ubuntu.* This is because *Ubuntu* does not primarily speak to global health, compared to SHG and GGH which were specifically designed to address global health inequities. However, *Ubuntu* requires that individuals within a community or defined group, work together to achieve a common good or a shared goal. Therefore, if *Ubuntu* was to be applied to global health, it would likely support a governance approach that seeks to address

health inequities and promote the common good. It is based on this that the FIHJ principle was adopted into the framework. Solidarity and reciprocity are also not promoted in all three governance theories. Reciprocity is promoted in *Ubuntu* only, while solidarity is promoted in *Ubuntu* and complemented by SHG (reflective solidarity). I kept these two principles because my overall goal was to develop a governance framework that is informed by norms and values shared by African populations. Also, the empirical data shows that, different stakeholders referred to *Ubuntu*, solidarity and reciprocity to justify their preference for certain governance processes.

As described in Chapter 7, a new principle that emerged from the empirical data (not originally part of our principles-based framework) is mutual respect. The initial framework was revised to include mutual respect as a core guiding principle. Mutual respect is the feeling shared between two or more people on the value or importance of something or someone. The principles of mutual respect, mutual trust, solidarity and reciprocity were often discussed together in the interviews, suggesting a link between them. Similar observations on the inter-relatedness of these principles have been put forth in the literature on global health research (Umoren et al., 2012, Hunt and Ridde, 2016, Tindana and de Vries, 2016, Merson et al., 2015).

The empirical data largely supported the frameworks principles and recommendations, but for a few points of divergence. For example, the document analysis showed that there was little involvement of study populations in decision making. Also, whilst the stakeholders that were interviewed acknowledged the importance of including this stakeholder group in policy development, they also expressed concerns about the practicability of such an approach. This may suggest that the Framework's recommendation to involve study populations in decision making may be challenging, from a practical point of view. Because the challenge was mainly a practical one but the overall recommendation received wide support, this particular recommendation was maintained in the revised Framework. Genomics research and biobanking consortia in Africa would have to actively identify appropriate ways of involving study populations in decision making and overall governance.

Public engagement is one approach that researchers can use to build public confidence and trust in health research (Daudelin et al., 2011, Samuel and Farsides, 2017). A key characteristic of public engagement is dialogue between "experts" (researchers) and the general public. It allows researchers to: listen to the public; gain an understanding of public views about certain biotechnologies, and incorporate these views in the implementation of their projects (Samuel and Farsides, 2017). There is a noticeable increase in community engagement in genomics research and biobanking projects in Africa (Campbell et al., 2015, Staunton et al., 2018, Mboowa et al., 2018, Jenkins et al., 2016, Rotimi et al., 2007). However, it appears that community engagement activities for genomics research in Africa have mainly focussed on: outreach

activities for specific diseases; ensuring that study procedures are sensitive to local beliefs and practices; and explaining concepts in genomics and biobanking with the goal of improving informed consent comprehension. However, little attention has been given to soliciting community views on policies for genomics research and biobanking. Whilst community engagement may, arguably, empower study populations to take part in decision making through improving public knowledge of genomics and biobanking, there is a critical need to go beyond that and to capture the voices of study communities when developing governance policies for research in which they are actively involved. This is because the long-term sustainability of genomics research and biobanking in Africa, as in other parts of the world, will no doubt depend on the acceptability of governance policies by all stakeholders, including study populations. This is key given the historical exploitation of these two stakeholder groups in global health research and structural inequities in health and health research between Africa and HICs. Whilst the voices of African researchers are increasingly being captured in the development of policies for genomics research and biobanking in Africa, the same cannot be said for study populations. Going forward, genomics research and biobanking consortia in Africa should seek to ensure that the voices of study communities are represented in decision making, a view that has been echoed by some researchers (Juengst and Meslin, 2019).

Mutual collective accountability (MCA) is another principle in the proposed framework where there was little mention of its practical implementation in H3Africa documents. There was equally some uncertainty from stakeholders on how it could be implemented. The interview data suggests that an independent organisation should be used for evaluating if the consortium is achieving its goals. However, MCA is about internal accountability and if some degree of accountability to an external body is expected, then the responsibilities of stakeholders to entities within and outside the consortium will have to be clearly defined. This is critical for transparency and also in building trust between African researchers and study communities. African researchers have an obligation to ensure that information on use of samples and data are fedback to study communities in ways that are comprehensible to the lay public. Another area where MCA is required but for which there was little information on its implementation is shared sovereignty. This requires monitoring if decision making processes are inclusive and meet the other requirements of shared sovereignty.

A final principle that requires some elaboration in its implementation is the principle of mutual trust. Trust is a person's reliance on someone or something to carry out their responsibilities or keep their promises (Beauchamp and Childress, 2001). Mutual trust requires that trust be shared by all parties involved in a shared activity. Trust is essential in addressing concerns of exploitation of African researchers and study populations (Jao et al., 2015, Pang, 2003, Sankoh and Ijsselmuiden, 2011, Moodley, 2017, Moodley and Singh, 2016, Parker et al., 2009).The empirical

data suggested that the level of trust decreases as one moves away from closed circles. This is to say that researchers are more likely to share data with researchers with whom they have already established a trusted research collaboration and also between African researchers. Whilst there is growing literature on the importance of mutual trust in global health research collaborations between HICs and African researchers, little is known about the role or importance of trust in research collaborations between African researchers and if they would automatically trust each other by virtue of being African researchers. This will benefit from future studies that broadly look at data sharing or equitable research collaborations between African researchers and whether trust and other principles in our framework should be given prominence.

8.2 Overall Study Limitations[23]

My insider status as a student in the H3Africa consortium may have constituted a significant source of bias in my analysis of the empirical data. As described in chapter 1 (Section 1.6; Researcher's Positionality), I received a PhD stipend from an H3Africa funded project and at some point also worked as a part-time research assistant for the H3Afica Ethics and Regulatory Issues Working Group. As a research assistant, I participated in the development of an H3Africa governance document. This document formed part of the empirical data. Also, one of my thesis supervisors is: the previous chair of the H3Africa ethics and regulatory issues working group; an H3Africa principal investigator; and a member of the H3Africa steering committee. Our position in H3Africa afforded us an opportunity to both to articulate the topic of this PhD and to give provide insight into why it mattered and how it could be done. It also allowed us to identify and access key interviewees. This probably motivated for the high response rate that I received for the in-depth interviews. However, it also meant that we were to some extent analysing the merits of our own work and could therefore have been biased. We sought to address this potential bias by 1) identifying the risk early on and committing to honesty and transparency in discussing it throughout the project and 2) appointing an external supervisor who had no prior involvement in H3Africa. We asked her to critically detect any possible bias as we carried out the research and interpreted the data. One that came up early on in the study, was that much reference was made to H3Africa when discussing genomics research projects in Africa. This was resolved by ensuring that we highlighted as much as possible, the activities of other human genomics research consortia in Africa (Section 1.2).

I used a case study approach to explore if the proposed governance framework is in line, or at par, with the everyday governance practices of genomics research and biobanking in Africa and

[23] Limitations specific to the empirical work (study population, access to documents and interviews) were described in Chapter 4, Section 4.4

if it met the expectations of the different stakeholders. This involved thematic analysis of H3Africa governance-related policies and one-on-one in-depth interviews with different H3Africa stakeholders. One of the major shortfalls from the interviews is that I did not include representatives from study populations, and therefore did not solicit their views in testing the governance framework. This was mainly for two reasons: Firstly, this stakeholder group had not been involved in the development of H3Africa governance policies. Secondly, whilst the H3Africa DBAC policy states that the DBAC has a representative of research participants, the first DBAC meeting took place towards the end of the data collection phase for this study. It would have been challenging to reach out to this representative at this time. Also, representatives of study communities had not previously been involved in developing H3Africa governance and may therefore have little insight into the governance practices of the consortium. Whilst it is important to test our principles against the views of this stakeholder group, they were relatively new to the consortium and had not been involved in any decision making or development of policies. However future studies should actively seek to explore the views and governance expectations of this stakeholder group.

8.3 Directions for Future Research

I had set out to understand how the ideals of justice could be advanced in genomics research and biobanking consortia in Africa. To do this, I had opted to articulate a governance framework whose principles speak to the justice-related ELSIs in genomics research and biobanking. Using a normative bioethics oriented approach, I developed a principles-based governance framework for genomics research and biobanking in Africa. The principles promoted in this conceptual framework were tested empirically using the reflective equilibrium approach.

This research unveiled further questions which could be investigated to enrich the discourse on justice and fairness in genomics research and biobanking in Africa. Firstly, one of the requirements of the shared sovereignty principle is that genomics research and biobanking consortia in Africa should involve study populations in decision making. This was supported by the different stakeholders that were interviewed. However, there are operational challenges to the implementation of this requirement. With the growing need to see research communities as partners in research, it will be important for future studies to identify practical and meaningful approaches for involving study populations in the governance of genomics research and biobanking in Africa. Further research should focus on developing models for science communication programs for genomics as well as models for meaningful involvement of study communities in decision making processes and governance as a whole.

Secondly, most of the principles promoted in the framework have separate requirements that would need to be fulfilled. For example, shared sovereignty has detailed requirements for

inclusivity, publicity, qualitative equality, deliberativeness, breadth, range and so forth. It was difficult to unpack, in detail, all these different requirements in a single study. Therefore, future studies that explore individual principles (alongside the different requirements of the principle), will throw more light on how the different requirements maybe achieved in the governance of genomics research and biobanking in Africa.

Thirdly, the interview data highlighted the importance of including study populations in decision making. However, the views of this stakeholder group were not captured in this study. It will be important for future studies to explore the involvement of study populations in decision making across different genomics research consortia to check if their views align with the principles promoted in the governance framework and to propose areas of revision where necessary.

Fourthly, there is a need to further explore the shared responsibility requirement especially in cases where the responsibilities are not clear at this time and where the primary responsibilities of African stakeholders has been shifted to HIC partners. A case in point is the responsibility of African governments in setting research priorities for genomics and in providing funding for such studies. This should include possible public engagement approaches for policy makers in Africa.

Also, the empirical data suggest that African leadership of genomics studies could minimise the exploitation of Africa researchers and study populations. Whilst H3Africa has adopted seems to have adopted this position, there is little evidence to support this claim. With a growing number of African-led global health programs in Africa, it will be important for future studies to check the for potential of African leadership of global health research collaborations to minimise exploitation, and the impact this may have on the governance of global health.

Lastly, the empirical aspect of this thesis focussed on the H3Africa consortium. H3Africa is a relatively well resourced genomics research and biobanking consortium and lots of efforts have gone into engaging different stakeholders and developing ethics policies. It is likely that the majority of the interviewees' opinions may have been influenced by the consortium's policies. Also, our interviewees constituted a small portion of the pool of stakeholders in genomics research and biobanking in Africa. In-depth interviews or surveys with non-H3Africa researchers in genomics or biobanking may shed light on the acceptability of our framework's principles for the broader pool of persons involved in genomics research and biobanking in Africa. This should also be extended to private and commercial initiatives involved in genomics research.

8.4 Conclusion

The overall aim of this study was to propose a governance framework for genomics research and biobanking in Africa that will address macro-level justice-related ELSIs in genomics research

collaborations in Africa. I wanted to develop a governance mechanism that is informed by principles and values that are likely to be shared by all stakeholders in genomics research in Africa and that allows for flexibility in its implementation.

Using the convergence approach and relying on two theories of global health justice (Shared health governance and global governance of health) as well as an African indigenous governance model, *Ubuntu*, I developed a principles-based governance framework for genomics research and biobanking in Africa. I suggest that the governance of genomics research and biobanking in Africa should be informed by the following principles: Solidarity; reciprocity; shared sovereignty; mutual respect; shared resources; furthering the ideals of health justice; shared responsibility; mutual collective accountability; transparency and mutual trust. I advocate for a governance mechanism whereby decision making is inclusive of all stakeholders especially research participants and study populations.

I also set out to develop a governance framework that is based on principles, yet not too abstract such that its implementation becomes challenging. For each principle therefore, I made recommendations on how they may be practically applied within genomics research and biobanking consortia. The framework's principles and requirements were broadly supported by stakeholders that were interviewed and also represented in the ethics governance documents of the H3Africa consortium. This would suggest that the principles and recommendations are largely in line with stakeholders' perceptions of how justice and fairness may be promoted in genomics research and biobanking.

Although the framework was developed to support the governance of genomics research and biobanking in Africa, its principles may be more broadly applicable to other global health research programs in Africa such as clinical trials and research on environmental and public health. The justice-related ethical issues in genomics research and biobanking arise as a result of the practice of sample and data sharing as well as storage of samples (and associated data) for future un-specified research. Whilst this is a common practice in genomics research and biobanking, it is fast becoming a characteristic of different kinds of health research. As such, I hope that the research reported in this thesis will support efforts aimed at promoting justice in global health research in general. Equally, whilst the framework developed in this thesis was meant to cater for the governance of genomics research in Africa, the normative analysis, particularly the convergence approach, showed that all the principles should apply to global health research in general. Therefore, the Framework will make a contribution to the governance of collaborative research globally.

References

ANDANDA, P. & LUCAS, J. C. 2007. Majengo HIV/AIDS Research Case. A Report for GenBenefit. *Benefit Sharing: From Biodiversity to Human Ethics.*

ANGELL, M. 1997. The ethics of clinical research in the Third World. *N Engl J Med,* 337**,** 847-9.

ANNAS, G. J. & GRODIN, M. A. 1998. Human rights and maternal-fetal HIV transmission prevention trials in Africa. *Am J Public Health,* 88**,** 560-3.

ARJOON, S. 2006. Striking a Balance Between Rules and Principles-based Approaches for Effective Governance: A Risks-based Approach. *Journal of Business Ethics,* 68**,** 53-82.

ARNSTEIN, S. R. 1969. A ladder of citizen participation. *Journal of the American Institute of planners,* 35**,** 216-224.

ARTHUR, D. D., ISSIFU, A. K. & MARFO, S. 2015. An Analysis of the Influence of Ubuntu Principle on the South Africa Peace Building Process.

AVARD, D., BUCCI, L. M., BURGESS, M. M., KAYE, J., HEENEY, C., FARMER, Y. & CAMBON-THOMSEN, A. 2009. Public health genomics (PHG) and public participation: points to consider. *Journal of public deliberation,* 5**,** 7.

AYITTEY, G. B. N. 2010. Traditional Institutions and the State of Accountability in Africa. *Social Research,* 77**,** 1183-1210.

BAILEY, T. C., MERRITT, M. W. & TEDIOSI, F. 2015. Investing in justice: ethics, evidence, and the eradication investment cases for lymphatic filariasis and onchocerciasis. *Am J Public Health,* 105**,** 629-36.

BALL, P. 2010. Bursting the genomics bubble. *Nature: International Weekly Journal of Science.* 31 March 2010 ed.

BALLANTYNE, A. 2005. HIV international clinical research: exploitation and risk. *Bioethics,* 19**,** 476-91.

BARCHI, F., MATLHAGELA, K., JONES, N., KEBAABETSWE, P. M. & MERZ, J. F. 2015. "The keeping is the problem": A qualitative study of IRB-member perspectives in Botswana on the collection, use, and storage of human biological samples for research. *BMC Medical Ethics,* 16**,** 54.

BATTLE, M. 2009. *Ubuntu: I in You and You in Me,* New York, Seabury Books.

BAXTER, P. & JACK, S. 2008. Qualitative case study methodology: Study design and implementation for novice researchers. *The qualitative report,* 13**,** 544-559.

BEAUCHAMP, T. L. & CHILDRESS, J. F. 2001. *Principles of Biomedical Ethics,* Oxford University Press.

BENATAR, S. & FLEISCHER, T. 2004. Ethical and policy implications of clinical drug trials con- ducted in developing countries. . *Harvard Health Policy Review,* 6**,** 9.

BENATAR, S. R. 1998. Imperialism, research ethics and global health. *Journal of Medical Ethics,* 24**,** 221.

BENATAR, S. R. 2000. Avoiding exploitation in clinical research. *Camb Q Healthc Ethics,* 9**,** 562-5.

BENATAR, S. R. 2001. Commentary: justice and medical research: a global perspective. *Bioethics,* 15**,** 333-40.

BENATAR, S. R. 2002. Human rights in the biotechnology era 1. *BMC International Health and Human Rights,* 2**,** 3-3.
BERNARD, H. R. 2017. *Research Methods in Anthropology: Qualitative and Quantitative Approaches*, Rowman & Littlefield Publishers.
BEZUIDENHOUT, L. 2018. To share or not to share…incentivizing data sharing in life science communities. *Developing World Bioethics,* 0.
BEZUIDENHOUT, L. & CHAKAUYA, E. 2018. Hidden concerns of sharing research data by low/middle-income country scientists. *Global bioethics = Problemi di bioetica,* 29**,** 39-54.
BHUTTA, Z. A. 2002. Ethics in international health research: a perspective from the developing world. *Bull World Health Organ,* 80**,** 114-20.
BIKO, S. 1987. Some African Cultural Concepts. *In:* STUBBS, A. (ed.) *I Write what I Like: A Selection of His Writings.* Heinemann.
BJORKMAN, B. 2007. Different types--different rights. Distinguishing between different perspectives on ownership of biological material. *Sci Eng Ethics,* 13**,** 221-33.
BLACK, J., HOPPER, M. & BAND, C. 2007. Making a success of Principles-based regulation. *Law and Financial Markets Review,* 1**,** 191-206.
BLANKENBERG, N. 1999. In search of a real freedom: Ubuntu and the media. *Critical Arts,* 13**,** 42-65.
BLIGH, M. C. 2017. Leadership and Trust. *In:* MARQUES, J. & DHIMAN, S. (eds.) *Leadership Today: Practices for Personal and Professional Performance.* Cham: Springer International Publishing.
BORRY, P., SCHOTSMANS, P. & DIERICKX, K. 2004. Empirical ethics: A challenge to bioethics. *Medicine, Health Care and Philosophy,* 7**,** 1-3.
BOULTON, G. 2012. Science as an Open Enterprise. London: The Royal Society.
BRICKMAN, P., FOLGER, R., GOODE, E. & SCHUL, Y. 1981. Microjustice and Macrojustice. *In:* LERNER, M. J. & LERNER, S. C. (eds.) *The Justice Motive in Social Behavior: Adapting to Times of Scarcity and Change.* Boston, MA: Springer US.
BROWN, A. 2014. Marx on Exploitation: A Kantian Perspective. *Rethinking Marxism,* 26**,** 360-381.
BRUEN, C., BRUGHA, R., KAGENI, A. & WAFULA, F. 2014. A concept in flux: questioning accountability in the context of global health cooperation. *Globalization and Health,* 10**,** 73.
BUDIN-LJØSNE, I., ISAEVA, J., MARIA KNOPPERS, B., MARIE TASSÉ, A., SHEN, H.-Y., MCCARTHY, M. I., CONSORTIUM, E. & HARRIS, J. R. 2014. Data sharing in large research consortia: experiences and recommendations from ENGAGE. *European Journal of Human Genetics,* 22**,** 317-321.
BULL, S., CHEAH, P. Y., DENNY, S., JAO, I., MARSH, V., MERSON, L., SHAH MORE, N., NHAN, L. N. T., OSRIN, D., TANGSEEFA, D., WASSENAAR, D. & PARKER, M. 2015. Best Practices for Ethical Sharing of Individual-Level Health Research Data From Low- and Middle-Income Settings. *Journal of Empirical Research on Human Research Ethics,* 10**,** 302-313.
BURGESS, G. J. 2017. Unpacking Inclusivity: Lessons from Ubuntu Leadership. *Breaking the Zero-Sum Game.* Emerald Publishing Limited.

BURGNER, D., JAMIESON, S. E. & BLACKWELL, J. M. 2006. Genetic susceptibility to infectious diseases: big is beautiful, but will bigger be even better? *Lancet Infect Dis,* 6**,** 653-63.

BUTROUS, G. 2015. International research collaboration: the key to combating pulmonary vascular diseases in the developing world. *Pulmonary Circulation,* 5**,** 413-414.

BYSKOV, J., MARCHAL, B., MALUKA, S., ZULU, J. M., BUKACHI, S. A., HURTIG, A.-K., BLYSTAD, A., KAMUZORA, P., MICHELO, C., NYANDIEKA, L. N., NDAWI, B., BLOCH, P. & OLSEN, Ø. E. 2014. The accountability for reasonableness approach to guide priority setting in health systems within limited resources – findings from action research at district level in Kenya, Tanzania, and Zambia. *Health Research Policy and Systems,* 12**,** 49.

CALLAHAN, D. 2003. Individual good and common good: a communitarian approach to bioethics. *Perspect Biol Med,* 46**,** 496-507.

CAMPBELL, M. C. & TISHKOFF, S. A. 2008. African genetic diversity: implications for human demographic history, modern human origins, and complex disease mapping. *Annual review of genomics and human genetics,* 9**,** 403-433.

CAMPBELL, M. M., SUSSER, E., DE VRIES, J., BALDINGER, A., SIBEKO, G., MNDINI, M. M., MQULWANA, S. G., NTOLA, O. A., RAMESAR, R. S. & STEIN, D. J. 2015. Exploring researchers' experiences of working with a researcher-driven, population-specific community advisory board in a South African schizophrenia genomics study. *BMC Medical Ethics,* 16**,** 45.

CARON-FLINTERMAN, J. F., BROERSE, J. E. & BUNDERS, J. F. 2005. The experiential knowledge of patients: a new resource for biomedical research? *Social science & medicine,* 60**,** 2575-2584.

CARR, D. & LITTLER, K. 2015. Sharing Research Data to Improve Public Health: A Funder Perspective. *Journal of Empirical Research on Human Research Ethics,* 10**,** 314-316.

CHAMBERS, S. 2003. Deliberative democratic theory. *Annual review of political science,* 6**,** 307-326.

CHANDRASEKHARAN, S. & COOK-DEEGAN, R. 2009. Gene patents and personalized medicine - what lies ahead? *Genome Medicine,* 1**,** 92.

CHARMAZ, K. 2006. *Constructing Grounded Theory: A Practical Guide Through Qualitative Analysis* London, UK, SAGE Publications Ltd.

CHEN, H. & PANG, T. 2015. A call for global governance of biobanks. *Bulletin of the World Health Organization,* 93**,** 113-117.

CHENNELLS, R. & STEENKAMP, A. 2018. International Genomics Research Involving the San People. *In:* SCHROEDER, D., COOK, J., HIRSCH, F., FENET, S. & MUTHUSWAMY, V. (eds.) *Ethics Dumping: Case Studies from North-South Research Collaborations.* Cham: Springer International Publishing.

CHI, Y. L. & BUMP, J. B. 2018. Resource allocation processes at multilateral organizations working in global health. *Health Policy and Planning,* 33**,** i4-i13.

CHIAL, H. 2008. DNA sequencing technologies key to the Human Genome Project. *Nature Education,* 1**,** 219.

CHOUDHURY, S., FISHMAN, J. R., MCGOWAN, M. L. & JUENGST, E. T. 2014. Big data, open science and the brain: lessons learned from genomics. *Frontiers in Human Neuroscience,* 8**,** 239.

CHU, K. M., JAYARAMAN, S., KYAMANYWA, P. & NTAKIYIRUTA, G. 2014. Building research capacity in Africa: equity and global health collaborations. *PLoS Med,* 11**,** e1001612.

COHEN, J. 2003. Deliberation and democratic legitimacy. *In:* MATRAVERS, D. & PIKE, J. (eds.) *Debates in Contemporary Political Philosophy. An Anthology.* New York: Routledge.

COHEN, J. & FUNG, A. 2004. Radical democracy. *Swiss journal of political science,* 10**,** 23-34.

COHRED 2000. Priority setting for health research: lessons from developing countries. The Working Group on Priority Setting. *Health Policy Plan,* 15**,** 130-6.

COLLINS, F. S., GREEN, E. D., GUTTMACHER, A. E. & GUYER, M. S. 2003. A vision for the future of genomics research. *Nature,* 422**,** 835-47.

COLLINS, F. S., PATRINOS, A., JORDAN, E., CHAKRAVARTI, A., GESTELAND, R. & WALTERS, L. 1998. New Goals for the U.S. Human Genome Project: 1998-2003. *Science,* 282**,** 682.

COOK-DEEGAN, R. & HEANEY, C. 2010. Patents in genomics and human genetics. *Annual review of genomics and human genetics,* 11**,** 383-425.

CORREA, C. M. 2009. 11 Intellectual Property Rights and Inequalities in Health Outcomes. *Globalization and health: Pathways, evidence and policy***,** 263.

CRANE, J. T. 2013. *Scrambling for Africa: AIDS, Expertise, and the Rise of American Global Health Science,* Cornell University Press.

CRESWELL, J. W. & POTH, C. N. 2016. *Qualitative Inquiry and Research Design: Choosing Among Five Approaches,* SAGE Publications.

DANIELS, N. 2000. Accountability for reasonableness : Establishing a fair process for priority setting is easier than agreeing on principles. *BMJ : British Medical Journal,* 321**,** 1300-1301.

DANIELS, N. 2001. Justice, health, and healthcare. *Am J Bioeth,* 1**,** 2-16.

DANIELS, N. 2016. Resource Allocation and Priority Setting. *In:* H. BARRETT, D., W. ORTMANN, L., DAWSON, A., SAENZ, C., REIS, A. & BOLAN, G. (eds.) *Public Health Ethics: Cases Spanning the Globe.* Cham: Springer International Publishing.

DANIELS, N. & SABIN, J. 1998. The ethics of accountability in managed care reform. *Health Affairs,* 17**,** 50-64.

DANIELS, N. & SABIN, J. E. 2008a. Accountability for reasonableness: an update. *BMJ,* 337.

DANIELS, N. & SABIN, J. E. 2008b. *Setting Limits Fairly: Learning to Share Resources for Health,* Oxford University Press.

DAUDA, B. 2017. African humanism and Ethics: The cases of Ubuntu and Omoluwabi. *In:* AFOLAYAN, A. & FALOLA, T. (eds.) *The Palgrave Handbook of African Philosophy.* USA: Palgrave Macmillan

DAUDELIN, G., LEHOUX, P., ABELSON, J. & DENIS, J. L. 2011. The integration of citizens into a science/policy network in genetics: governance arrangements and asymmetry in expertise. *Health Expect,* 14**,** 261-71.

DAVIES, R., IVES, J. & DUNN, M. 2015. A systematic review of empirical bioethics methodologies. *BMC Med Ethics,* 16**,** 15.

DE MENIL, V., HOOGENHOUT, M., KIPKEMOI, P., KAMUYA, D., EASTMAN, E., GALVIN, A., MWANGASHA, K., DE VRIES, J., KARIUKI, S. M., MURUGASEN, S., MWANGI, P., SINGH, I., STEIN, D. J., ABUBAKAR, A., NEWTON, C. R., DONALD,

K. A. & ROBINSON, E. 2019. The NeuroDev Study: Phenotypic and Genetic Characterization of Neurodevelopmental Disorders in Kenya and South Africa. *Neuron,* 101**,** 15-19.

DE VRIES, J., ABAYOMI, A., LITTLER, K., MADDEN, E., MCCURDY, S., OUKEM-BOYER, O. O. M., SEELEY, J., STAUNTON, C., TANGWA, G. & TINDANA, P. 2015a. Addressing ethical issues in H3Africa research–the views of research ethics committee members. *The HUGO Journal,* 9**,** 1.

DE VRIES, J., BULL, S. J., DOUMBO, O., IBRAHIM, M., MERCEREAU-PUIJALON, O., KWIATKOWSKI, D. & PARKER, M. 2011. Ethical issues in human genomics research in developing countries. *BMC Medical Ethics,* 12**,** 1-10.

DE VRIES, J., JALLOW, M., WILLIAMS, T. N., KWIATKOWSKI, D., PARKER, M. & FITZPATRICK, R. 2012. Investigating the potential for ethnic group harm in collaborative genomics research in Africa: Is ethnic stigmatisation likely? *Social science & medicine (1982),* 75**,** 1400-1407.

DE VRIES, J., MUNUNG, S. N., MATIMBA, A., MCCURDY, S., OUWE MISSI OUKEM-BOYER, O., STAUNTON, C., YAKUBU, A. & TINDANA, P. 2017. Regulation of genomic and biobanking research in Africa: a content analysis of ethics guidelines, policies and procedures from 22 African countries. *BMC Medical Ethics,* 18**,** 8.

DE VRIES, J. & PEPPER, M. 2012. Genomic sovereignty and the African promise: mining the African genome for the benefit of Africa. *J Med Ethics,* 38**,** 474-8.

DE VRIES, J., TINDANA, P., LITTLER, K., RAMSAY, M., ROTIMI, C., ABAYOMI, A., MULDER, N. & MAYOSI, B. M. 2015b. The H3Africa policy framework: negotiating fairness in genomics. *Trends in genetics : TIG,* 31**,** 117-119.

DE VRIES, J., TINDANA, P., LITTLER, K., RAMSAY, M., ROTIMI, C., ABAYOMI, A., MULDER, N. & MAYOSI, B. M. 2015c. The H3Africa policy framework: negotiating fairness in genomics. *Trends Genet,* 31**,** 117-9.

DE VRIES, M. & VAN LEEUWEN, E. 2010. Reflective equilibrium and empirical data: third person moral experiences in empirical medical ethics. *Bioethics,* 24**,** 490-8.

DE VRIES, P. J. 2017. Meeting the complex needs of individuals with rare genetic disorders in South Africa - lessons from tuberous sclerosis complex. *SAMJ: South African Medical Journal,* 107**,** 366-367.

DEAN, J. 1998. Feminist Solidarity, Reflective Solidarity. *Women & Politics,* 18**,** 1-26.

DENZIN, N. K. & LINCOLN, Y. S. 2005. *The SAGE Handbook of Qualitative Research,* Sage Publications.

DEVERS, K. J. & FRANKEL, R. M. 2000. Study design in qualitative research--2: Sampling and data collection strategies. *Education for health,* 13**,** 263.

DISTEFANO, M. & RUGER, J. P. 2015. Reflective Solidarity as to Provincial Globalism and Shared Health Governance. *Diametros,* 46**,** 151-158.

DOLAMO, R. 2014. Botho/Ubuntu: The Heart of African Ethics. *2014,* 112**,** 10.

DRAPER, H. & IVES, J. 2007. An Empirical Approach to Bioethics: Social Science"of", "for" and "in" Bioethics Research. *Cognitie, Creier, Comportament/Cognition, Brain, Behavior,* 11.

DRY, S. M., GARRETT, S. B., KOENIG, B. A., BROWN, A. F., BURGESS, M. M., HULT, J. R., LONGSTAFF, H., WILCOX, E. S., MADRIGAL CONTRERAS, S. K., MARTINEZ, A., BOYD, E. A. & DOHAN, D. 2017. Community recommendations on biobank

governance: Results from a deliberative community engagement in California. *PLOS ONE,* 12**,** e0172582.
DRYZEK, J. S. & NIEMEYER, S. 2012. *Foundations and Frontiers of Deliberative Governance,* Oxford, Oxford University Press.
DU TOIT, C. 2005. Technoscience and the Integrity of Personhood in Africa and the West: Facing our Technoscientific Environment. *HTS,* 61**,** 829-860.
DUMAY, J. & QU, S. Q. 2011. The qualitative research interview. *Qualitative Research in Accounting & Management,* 8**,** 238-264.
DYE, C., REEDER, J. & TERRY, R. 2013a. Research for universal health coverage. *Science translational medicine,* 5**,** 199ed13.
DYE, C., REEDER, J. C. & TERRY, R. F. 2013b. Research for universal health coverage. *Sci Transl Med,* 5**,** 199ed13.
EISENBERG, R. S. 1990. Patenting the human genome. *Emory Law J,* 39**,** 721-45.
EMANUEL, E. J., WENDLER, D., KILLEN, J. & GRADY, C. 2004. What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research. *The Journal of Infectious Diseases,* 189**,** 930-937.
FECHER, B., FRIESIKE, S. & HEBING, M. 2015. What Drives Academic Data Sharing? *PLOS ONE,* 10**,** e0118053.
FIDLER, D. P. 2007. Indonesia's Decision to Withhold Influenza Virus Samples from the World Health Organization: Implications for International Law. *Insight.* American Society of International Law.
FISHKIN, J. S. 2011. *When the people speak: Deliberative democracy and public consultation,* Oxford, Oxford University Press.
FRANKLIN, N. 2009. Sovereignty and international politics in the negotiation of the avian influenza Material Transfer Agreement. *Journal of law and medicine,* 17**,** 355-372.
FREUDENTHAL, E. 2019. Ebola's lost blood: row over samples flown out of Africa as 'big pharma' set to cash in *The Telegraph*, 06 February 2019.
FRIEDRICH, M. J. 2015. African Genome Variation Project Will Facilitate Genetic Studies in AfricaAfrican Genome Variation ProjectGlobal Health. *JAMA,* 313**,** 659-659.
FULLERTON, S. M., ANDERSON, N. R., GUZAUSKAS, G., FREEMAN, D. & FRYER-EDWARDS, K. 2010. Meeting the Governance Challenges of Next-Generation Biorepository Research. *Science Translational Medicine,* 2**,** 15cm3.
GFHR 2004. 10/90 Report on Health Research 2003-2004. Geneva, Switzerland: : Global Forum for Health Research.
GFHR 2008. The Bamako call to action: research for health. *The Lancet,* 372**,** 1855.
GOETZ, A. M. & JENKINS, R. 2002. Voice, Accountability and Human Development: The Emergence of a New Agenda, . *Human Development Occasional Papers (1992-2007).* United Nations Development Programme.
GOMEZ-DANTS, O. & FRENK, J. 2015. The Quest for Global Justice in Health: A Review of Global Health Law by Lawrence 0. Gostin. *Yale Journal of Health Policy, Law, and Ethics,* 15**,** 4.
GOMEZ, F., HIRBO, J. & TISHKOFF, S. A. 2014. Genetic variation and adaptation in Africa: implications for human evolution and disease. *Cold Spring Harbor perspectives in biology,* 6**,** a008524-a008524.
GOSLING, M. 2017. Nairobi sex workers want a research code of conduct

GOSTIN, L., HEYWOOD, M., OOMS, G., RØTTINGEN, J.-A., MØGEDAL, S., HAFFELD, J., FRIEDMAN, E. A. & SIEM, H. 2010. The Joint Action and Learning Initiative on National and Global Responsibilities for Health.

GOSTIN, L., MOK, E. & FRIEDMAN, E. 2011. Towards a radical transformation in global governance for health. *Michael,* 8**,** 228-39.

GOSTIN, L. O. 2007. Meeting the survival needs of the world's least healthy people: a proposed model for global health governance. *JAMA,* 298**,** 225-8.

GOSTIN, L. O. 2008. Meeting basic survival needs of the world's least healthy people: Toward a framework convention on global health. *The Goergetown Law Journal,* 96**,** 331-392.

GOSTIN, L. O. 2014. *Global Health Law*, Harvard University Press.

GOSTIN, L. O. & FRIEDMAN, E. A. 2013. Towards a Framework Convention on Global Health: a transformative agenda for global health justice. *Yale J Health Policy Law Ethics,* 13**,** 1-75.

GOSTIN, L. O., FRIEDMAN, E. A., BUSE, K., WARIS, A., MULUMBA, M., JOEL, M., DARE, L., DHAI, A. & SRIDHAR, D. 2013. Towards a framework convention on global health. *Bulletin of the World Health Organization,* 91**,** 790-793.

GOSTIN, L. O. & MOK, E. A. 2009. Grand challenges in global health governance. *British Medical Bulletin,* 90**,** 7-18.

GOSTIN, L. O. & TAYLOR, A. L. 2008. Global health law: A definition and grand challenges. *Public Health Ethics,* 1**,** 53-63.

GREEN, A. K., REEDER-HAYES, K. E., CORTY, R. W., BASCH, E., MILOWSKY, M. I., DUSETZINA, S. B., BENNETT, A. V. & WOOD, W. A. 2015. The project data sphere initiative: accelerating cancer research by sharing data. *Oncologist,* 20**,** 464-e20.

GURDASANI, D., CARSTENSEN, T., TEKOLA-AYELE, F., PAGANI, L., TACHMAZIDOU, I., HATZIKOTOULAS, K., KARTHIKEYAN, S., ILES, L., POLLARD, M. O., CHOUDHURY, A., RITCHIE, G. R. S., XUE, Y., ASIMIT, J., NSUBUGA, R. N., YOUNG, E. H., POMILLA, C., KIVINEN, K., ROCKETT, K., KAMALI, A., DOUMATEY, A. P., ASIKI, G., SEELEY, J., SISAY-JOOF, F., JALLOW, M., TOLLMAN, S., MEKONNEN, E., EKONG, R., OLJIRA, T., BRADMAN, N., BOJANG, K., RAMSAY, M., ADEYEMO, A., BEKELE, E., MOTALA, A., NORRIS, S. A., PIRIE, F., KALEEBU, P., KWIATKOWSKI, D., TYLER-SMITH, C., ROTIMI, C., ZEGGINI, E. & SANDHU, M. S. 2015. The African Genome Variation Project shapes medical genetics in Africa. *Nature,* 517**,** 327-332.

H3AFRICA. 2013. *http://h3africa.org/consortium/projects* [Online]. [Accessed 31 March 2015].

H3AFRICA CONSORTIUM 2014. Enabling the genomic revolution in Africa. *Science,* 344**,** 1346-1348.

HAMMOND, E. 2009. Indonesia fights to change WHO rules on flu vaccines. *Grain.* https://www.grain.org/article/entries/761-indonesia-fights-to-change-who-rules-on-flu-vaccines.

HARDIN, R. 2002. *Trust and Trustworthiness,* Russell Sage Foundation.

HAWKINS, J. S. & EMANUEL, E. J. 2008. *Exploitation and Developing Countries. The Ethics of Clinical Research,* Princeton University Press.

HEYMANN, D. L., LIU, J. & LILLYWHITE, L. 2016. Partnerships, Not Parachutists, for Zika Research. *N Engl J Med,* 374**,** 1504-5.

HONDERICH, T. 1995. *The Oxford Companion to Philosophy,* Oxford University Press.

HOOD, L. & ROWEN, L. 2013. The Human Genome Project: big science transforms biology and medicine. *Genome Med,* 5**,** 79.

HOPKINS, M., MAHDI, S., THOMAS, S. & PATEL, P. 2006. The patenting of human DNA: Global trends in public and private sector activity (the PATGEN Project). *A report for the European Commission, compiled by Science Policy Research Unit, University of Sussex, Brighton, UK, November*.

HORNE, D. L. 2004. *Meeting Ma'at: The African Centered Handbook for Conducting Meetings,* Bloomington, Indiana, AuthorHouse.

HUFTY, M. 2011. Investigating policy processes: the governance analytical framework (GAF). *In:* WIESMANN, U. & HURNI, H. (eds.) *Research for Sustainable Development: Foundations, Experiences and Perspectives* Geographica Bernensia.

HUGO ETHICS COMMITTEE 2000. Hugo Ethics Committee statement on benefit sharing. *Clinical Genetics,* 58**,** 364-366.

HUNT, M. R. & GODARD, B. 2013. Beyond procedural ethics: foregrounding questions of justice in global health research ethics training for students. *Glob Public Health,* 8**,** 713-24.

HUNT, M. R. & RIDDE, V. 2016. NGO–researcher partnerships in global health research: benefits, challenges, and approaches that promote success AU - Olivier, Catherine. *Development in Practice,* 26**,** 444-455.

IGBE, M. A. & ADEBAMOWO, C. A. 2012. Qualitative study of knowledge and attitudes to biobanking among lay persons in Nigeria. *BMC Medical Ethics,* 13**,** 27.

IJSSELMUIDEN, C. B., KASS, N. E., SEWANKAMBO, K. N. & LAVERY, J. V. 2010. Evolving values in ethics and global health research. *Glob Public Health,* 5**,** 154-63.

IVES, J. & DRAPER, H. 2009. Appropriate methodologies for empirical bioethics: it's all relative. *Bioethics,* 23**,** 249-58.

IVES, J., M., D. & CRIBB, A. 2016. *Empirical Bioethics: Theoretical and Practical Perspectives,* Cambridge, Cambridge University Press.

JACOB, S. A. & FURGERSON, S. P. 2012. Writing interview protocols and conducting interviews: Tips for students new to the field of qualitative research. *The Qualitative Report,* 17**,** 1-10.

JAO, I., KOMBE, F., MWALUKORE, S., BULL, S., PARKER, M., KAMUYA, D., MOLYNEUX, S. & MARSH, V. 2015. Research Stakeholders' Views on Benefits and Challenges for Public Health Research Data Sharing in Kenya: The Importance of Trust and Social Relations. *PLOS ONE,* 10**,** e0135545.

JENKINS, C., ARULOGUN, O. S., SINGH, A., MANDE, A. T., AJAYI, E., CALYS-TAGOE, B., OVBIAGELE, B., LACKLAND, D. T., SARFO, F. S., AKINYEMI, R., AKPALU, A., OBIAKO, R., MELIKAM, E. S., LARYEA, R., SHIDALI, V., SAGOE, K., IBINAIYE, P., FAKUNLE, A. G., OWOLABI, L. F. & OWOLABI, M. O. 2016. Stroke Investigative Research and Education Network: Community Engagement and Outreach Within Phenomics Core. *Health Educ Behav,* 43**,** 82s-92s.

JENTSCH, B. & PILLEY, C. 2003. Research relationships between the South and the North: Cinderella and the ugly sisters? *Soc Sci Med,* 57**,** 1957-67.

JUENGST, E. T. & MESLIN, E. M. 2019. Sharing with Strangers: Governance Models for Borderless Genomic Research in a Territorial World. *Kennedy Institute of Ethics Journal,* 29**,** 67-95.

KAGAME, A. 1976. *La philosophie bantu comparée,* Paris, Présence Africaine.

KAWULICH, B. B. Participant observation as a data collection method. Forum Qualitative Sozialforschung/Forum: Qualitative Social Research, 2005.
KAYE, J., HEENEY, C., HAWKINS, N., DE VRIES, J. & BODDINGTON, P. 2009. Data sharing in genomics--re-shaping scientific practice. *Nat Rev Genet,* 10**,** 331-5.
KEAN, S. 2011. The Human Genome (Patent) Project. *Science,* 331**,** 530.
KHOMBA, J. K., BAKUWA, R. C. & KANGAUDE-ULAYA, E. C. 2013. Shaping business ethics and corporate governance: An inclusive African Ubuntu Philosophy. *Global Journal of Management And Business Research,* 13**,** 30-42.
KHOURY, M. J. 2003. Genetics and genomics in practice: the continuum from genetic disease to genetic information in health and disease. *Genet Med,* 5**,** 261-8.
KHOZA, R. J. 2006. *Let Africa Lead: African Transformational Leadership for 21st Century Business,* Vezubuntu.
KHOZA, R. J. 2012. The Ubuntu Philosophy as a Conceptual Framework for Interpersonal Relationships and Leadership. 15 Spetember 2012 ed.
KLEINGELD, P. & BROWN, E. 2014. Cosmopolitanism. *In:* ZALTA, E. N. (ed.) *The Stanford Encyclopedia of Philosophy* https://plato.stanford.edu/archives/fall2014/entries/cosmopolitanism/.
KNOPPERS, B. M. 2000. Population genetics and benefit sharing. *Community Genet,* 3**,** 212-4.
KOK, M. O., GYAPONG, J. O., WOLFFERS, I., OFORI-ADJEI, D. & RUITENBERG, E. J. 2017. Towards fair and effective North–South collaboration: realising a programme for demand-driven and locally led research. *Health Research Policy and Systems,* 15**,** 96.
KRUBINER, C. B. & MERRITT, M. W. 2017. Which strings attached: ethical considerations for selecting appropriate conditionalities in conditional cash transfer programmes. *J Med Ethics,* 43**,** 167-176.
KUMAR, S., KUMAR, N. & VIVEKADHISH, S. 2016. Millennium Development Goals (MDGs) to Sustainable Development Goals (SDGs): Addressing Unfinished Agenda and Strengthening Sustainable Development and Partnership. *Indian Journal of Community Medicine : Official Publication of Indian Association of Preventive & Social Medicine,* 41**,** 1-4.
KVALE, S. 1996. *Interviews: An Introduction to Qualitative Research Interviewing,* Thousand Oaks California, Sage Publications Inc.
LAIRUMBI, G. M., PARKER, M., FITZPATRICK, R. & ENGLISH, M. C. 2012. Forms of benefit sharing in global health research undertaken in resource poor settings: a qualitative study of stakeholders' views in Kenya. *Philosophy, Ethics, and Humanities in Medicine,* 7**,** 7.
LAIRUMBI, G. M., PARKER, M., FITZPATRICK, R. & MIKE, E. C. 2011. Stakeholders understanding of the concept of benefit sharing in health research in Kenya: a qualitative study. *BMC Medical Ethics,* 12**,** 1-9.
LAURIE, G. & SETHI, N. 2013. Towards Principles-Based Approaches to Governance of Health-related Research using Personal Data. *European journal of risk regulation : EJRR,* 4**,** 43-57.
LEE, K. & MILLS, A. 2000. Strengthening governance for global health research. *Bmj,* 321**,** 775-6.
LETSEKA, M. 2014. Ubuntu and justice as fairness. *Mediterranean journal of social sciences,* 5**,** 544-551.

LONDON, A. J. 2005. Justice and the human development approach to international research. *Hastings Cent Rep,* 35**,** 24-37.

LOUW, D. J. 2001. Ubuntu and the challenges of multiculturalism in post-apartheid South Africa. *QUEST-An African Journal of Philosophy,* XV**,** 15-36.

LOUW, D. J. 2002. *Ubuntu and the Challenges of Multiculturalism in Post-apartheid South Africa,* Expertisecentrum Zuidelijk Afrika.

LUCAS, J. C., SCHROEDER, D., ARNASON, G., ANDANDA, P., KIMANI, J., FOURNIER, V. & KRISHNAMURTHY, M. 2013. Donating Human Samples: Who Benefits? Cases from Iceland, Kenya and Indonesia. *In:* SCHROEDER, D. & COOK LUCAS, J. (eds.) *Benefit Sharing: From Biodiversity to Human Genetics.* Dordrecht: Springer Netherlands.

LUTZ, D. W. 2009. African "Ubuntu" Philosophy and Global Management. *Journal of Business Ethics,* 84**,** 313-328.

MACK, N., WOODSONG, C., MACQUEEN, K. M., GUEST, G. & NAMEY, E. 2005. Qualitative Research Methods Overview. *Qualitative Research Methods: A Data Collector's Field Guide.* North Carolina: Family Health International.

MANDELA, N. 2006. Foreword. *In:* KHOZA, R. J. (ed.) *Let Africa Lead: African Transformational Leadership for 21st Century Business.* Johannesburg: Vezubuntu.

MASIYE, F., MAYOSI, B. & DE VRIES, J. 2017. "I passed the test!" Evidence of diagnostic misconception in the recruitment of population controls for an H3Africa genomic study in Cape Town, South Africa. *BMC Med Ethics,* 18**,** 12.

MBIGI, L. & MAREE, J. 1995. *Ubuntu, the spirit of African transformation management,* California, Knowledge Resources.

MBITI, J. S. 1968. *African Religions and Philosophy,* London, Heinemann.

MBOOWA, G., MWESIGWA, S., KATAGIRYA, E., RETSHABILE, G., MLOTSHWA, B. C., WILLIAMS, L., KEKITIINWA, A., KATEETE, D., WAMPANDE, E., WAYENGERA, M., KINTU, B. N., KISITU, G. P., KYOBE, S., BROWN, C. W., HANCHARD, N. A., MARDON, G., JOLOBA, M., ANABWANI, G., PETTITT, E., TSIMAKO-JOHNSTONE, M., KASVOSVE, I., MAPLANKA, K., MPOLOKA, S. W., HLATSHWAYO, M. & MATSHABA, M. 2018. The Collaborative African Genomics Network (CAfGEN): Applying Genomic technologies to probe host factors important to the progression of HIV and HIV-tuberculosis infection in sub-Saharan Africa [version 2; referees: 2 approved]. *AAS Open Res* 1.

MCCARTY, C. A., GARBER, A., REESER, J. C. & FOST, N. C. 2011. Study newsletters, community and ethics advisory boards, and focus group discussions provide ongoing feedback for a large biobank. *Am J Med Genet A,* 155a**,** 737-41.

MCUNU, T. N. 2004. *The dignity of the human person : a contribution of the theology of ubuntu to theological anthropology.*

MELDRUM, D. R. 1995. Engineering in genomics: the interdisciplinary nature of genomics. *IEEE Engineering in Medicine and Biology Magazine,* 14**,** 443-448.

MERSON, L., PHONG, T. V., NHAN, L. N. T., DUNG, N. T., NGAN, T. T. D., KINH, N. V., PARKER, M. & BULL, S. 2015. Trust, Respect, and Reciprocity: Informing Culturally Appropriate Data-Sharing Practice in Vietnam. *Journal of empirical research on human research ethics : JERHRE,* 10**,** 251-263.

METZ, T. 2007. Toward an African Moral Theory. *Journal of Political Philosophy,* 15**,** 321-341.

MICHAEL, M., ANNE, T., SUSAN, M. C., NATASHA DAMIANO, P. & DARQUISE, L. 2008. Trust in Health Research Relationships: Accounts of Human Subjects. *Journal of Empirical Research on Human Research Ethics,* 3**,** 35-47.

MILES, M. B. & HUBERMAN, A. M. 1994. *Qualitative Data Analysis: An Expanded Sourcebook,* SAGE Publications.

MILES, M. B., HUBERMAN, A. M., HUBERMAN, M. A. & HUBERMAN, P. M. 1994. *Qualitative Data Analysis: An Expanded Sourcebook,* London, SAGE Publications.

MKHIZE, N. 2008. Ubuntu and harmony : an African approach to morality and ethics. *In:* NICOLSON, R. (ed.) *Persons in Community: African Ethics in a Global Culture.* Pietermaritzburg: University of Kwazulu-Natal Press.

MOLYNEUX, S. & GEISSLER, P. W. 2008. Ethics and the ethnography of medical research in Africa. *Social Science & Medicine (1982),* 67**,** 685-695.

MONTSERRAT MOLINER, A. & WALIGÓRA, J. 2013. The European Union Policy in the Field of Rare Diseases. *Public Health Genomics,* 16**,** 268-277.

MOODLEY, K. 2017. Legitimacy, Trust and Stakeholder Engagement: Biobanking in South Africa. *Asian Bioethics Review,* 9**,** 325-334.

MOODLEY, K., SIBANDA, N., FEBRUARY, K. & ROSSOUW, T. 2014. "It's my blood": ethical complexities in the use, storage and export of biological samples: perspectives from South African research participants. *BMC Medical Ethics,* 15**,** 4.

MOODLEY, K. & SINGH, S. 2016. "It's all about trust": reflections of researchers on the complexity and controversy surrounding biobanking in South Africa. *BMC Medical Ethics,* 17**,** 57.

MSILA, V. 2015. *UBUNTU: Shaping the current workplace with (African) wisdom,* Randburg, South Africa, Knowres Publishing.

MULDER, N., ADEBAMOWO, C. A., ADEBAMOWO, S. N., ADEBAYO, O., ADELEYE, O., ALIBI, M., BAICHOO, S., BENKAHLA, A., FADLELMOLA, F. M. & GHAZAL, H. 2017. Genomic research data generation, analysis and sharing–challenges in the African setting. *Data Science Journal,* 16**,** 1-15.

MUNUNG, N. S. 2016. *African Researchers' Perceptions and Expectations of the Benefits of Genomics Research in Africa: A Qualitative Study.* MSc. Med (Bioethics), University of Cape Town.

MUNUNG, N. S., MARSHALL, P., CAMPBELL, M., LITTLER, K., MASIYE, F., OUWE-MISSI-OUKEM-BOYER, O., SEELEY, J., STEIN, D. J., TINDANA, P. & DE VRIES, J. 2016. Obtaining informed consent for genomics research in Africa: analysis of H3Africa consent documents. *Journal of Medical Ethics,* 42**,** 132.

MUNUNG, N. S., MAYOSI, B. M. & DE VRIES, J. 2017. Equity in international health research collaborations in Africa: Perceptions and expectations of African researchers. *PLOS ONE,* 12**,** e0186237.

MUNUNG, N. S., MAYOSI, B. M. & DE VRIES, J. 2018. Genomics research in Africa and its impact on global health: insights from African researchers. *Global Health, Epidemiology and Genomics,* 3**,** e12.

MUSOLINO, N., LAZDINS, J., TOOHEY, J. & C, I. J. 2015. COHRED Fairness Index for international collaborative partnerships. *Lancet,* 385**,** 1293-4.

MUSSCHENGA, A. W. 2005. Empirical ethics, context-sensitivity, and contextualism. *J Med Philos,* 30**,** 467-90.

NCOB 2002. The ethics ofpatenting DNA: A discussion paper. London, UK: Nuffield Council on Bioethics.
NEED, A. C. & GOLDSTEIN, D. B. 2009. Next generation disparities in human genomics: concerns and remedies. *Trends Genet,* 25**,** 489-94.
NEWPORT, M. J. & ROTIMI, C. N. 2009. Reducing the global genomic inequity gap: development of an african genome project. *Public Health Genomics,* 12**,** 251-2.
NG, N. Y. & RUGER, J. P. 2011. Global Health Governance at a Crossroads. *Global health governance : the scholarly journal for the new health security paradigm,* 3**,** 1-37.
NIENABER, A. 2011. Consent to and authorisation of the export and use of human biological specimens for future research — perspectives from three African countries. *The Comparative and International Law Journal of Southern Africa,* 44**,** 225-254.
NORDLING, L. 2012. African Researchers Sue Flagship Programme for Discrimination. *Nature News* 487:.
NUSSBAUM, B. 2003. Ubuntu: Reflections of a South African on our common humanity. *Reflections: The SoL Journal,* 4**,** 21-26.
NYERERE, J. K. 1968. *Ujamaa [engl.] Essays on socialism*, Oxford University Press.
NYIKA, A. 2009. Ethical and practical challenges surrounding genetic and genomic research in developing countries. *Acta Tropica,* 112, Supplement 1**,** S21-S31.
NZIMAKWE 2014. Practising Ubuntu and leadership for good governance : the South African and continental dialogue. *African Journal of Public Affairs,* 7**,** 30-41.
O'BRIEN, S. J. 2009. Stewardship of human biospecimens, DNA, genotype, and clinical data in the GWAS era. *Annu Rev Genomics Hum Genet,* 10**,** 193-209.
O'DOHERTY, K. C., HAWKINS, A. K. & BURGESS, M. M. 2012. Involving citizens in the ethics of biobank research: informing institutional policy through structured public deliberation. *Soc Sci Med,* 75**,** 1604-11.
OGUNRIN, O., WOOLFALL, K., GABBAY, M. & FRITH, L. 2018. Relative solidarity: Conceptualising communal participation in genomic research among potential research participants in a developing Sub-Saharan African setting. *PLOS ONE,* 13**,** e0195171.
OKEKE, I. N. 2016. African biomedical scientists and the promises of "big science". *Canadian Journal of African Studies / Revue canadienne des études africaines,* 50**,** 455-478.
OKWARO, M. F. & GEISSLER, P. W. 2015. In/dependent Collaborations: Perceptions and Experiences of African Scientists in Transnational HIV Research. *Medical Anthropology Quarterly,* 29**,** 492-511.
OPPENHEIM, C. E. 2012. Nelson Mandela and the Power of Ubuntu. *Religions,* 3.
OSABU-KLE, D. T. 2000. *Compatible Cultural Democracy:The Key to Development in Africa,* University of Toronto Press.
PALSSON, G. 2008. The rise and fall of a biobank: the case of Iceland. *In:* GOTTWEIS, H. & PETERSEN, A. (eds.) *Biobanks: governance in comparative perspective.* London: Routledge.
PANG, T. 2002. The Impact of Genomics on Global Health. *American Journal of Public Health,* 92**,** 1077-1079.
PANG, T. 2003. Equal partnership to ensure that developing countries benefit from genomics. *Nat Genet,* 33**,** 18.

PANG, T., SADANA, R., HANNEY, S., BHUTTA, Z. A., HYDER, A. A. & SIMON, J. 2003. Knowledge for better health: a conceptual framework and foundation for health research systems. *Bull World Health Organ,* 81**,** 815-20.

PARKER, M., BULL, S. J., DE VRIES, J., AGBENYEGA, T., DOUMBO, O. K. & KWIATKOWSKI, D. P. 2009. Ethical Data Release in Genome-Wide Association Studies in Developing Countries. *PLoS Medicine,* 6**,** e1000143.

PARKER, M. & KINGORI, P. 2016. Good and Bad Research Collaborations: Researchers' Views on Science and Ethics in Global Health Research. *PLOS ONE,* 11**,** e0163579.

PARKER, M. & KWIATKOWSKI, D. P. 2016. The ethics of sustainable genomic research in Africa. *Genome Biology,* 17**,** 44.

PATTON, M. Q. 1990. *Qualitative evaluation and research methods, 2nd ed,* Thousand Oaks, CA, US, Sage Publications, Inc.

PEPPER, M. S. 2011. Launch of the Southern African Human Genome Programme. *S Afr Med J,* 101**,** 287-8.

PEPPER, M. S., DANDARA, C., DE VRIES, J., DHAI, A., LABUSCHAIGNE, M., MNYONGANI, F., MOODLEY, K., OLCKERS, A., POPE, A., RAMESAR, R., RAMSAY, M., SOODYALL, H. & TOWERS, W. 2018. ASSAf consensus study on the ethical, legal and social implications of genetics and genomics in South Africa. *South African Journal of Science,* 114**,** 1-3.

PISANI, E., WHITWORTH, J., ZABA, B. & ABOU-ZAHR, C. 2010. Time for fair trade in research data. *The Lancet,* 375**,** 703-705.

POGGE, T. & MOELLENDORF, D. 2008. *Global Justice: Seminal Essays,* Paragon House.

POPEJOY, A. B. & FULLERTON, S. M. 2016. Genomics is failing on diversity. *Nature,* 538**,** 161-164.

POUND, P. & CAMPBELL, R. 2015. Exploring the feasibility of theory synthesis: A worked example in the field of health related risk-taking. *Social Science & Medicine,* 124**,** 57-65.

PRAINSACK, B. & BUYX, A. 2012. Solidarity in Contemporary Bioethics – Towards a new approach. *Bioethics,* 26**,** 343-350.

PRATT, B., ALLEN, K. A. & HYDER, A. A. 2016a. Promoting equity through health systems research in low- and middle-income countries: Practices of researchers. *AJOB Empirical Bioethics,* 7**,** 199-208.

PRATT, B. & HYDER, A. A. 2015. Global justice and health systems research in low- and middle-income countries. *J Law Med Ethics,* 43**,** 143-61.

PRATT, B. & HYDER, A. A. 2016. Governance of Transnational Global Health Research Consortia and Health Equity. *Am J Bioeth,* 16**,** 29-45.

PRATT, B. & HYDER, A. A. 2017. Governance of global health research consortia: Sharing sovereignty and resources within Future Health Systems. *Social Science & Medicine,* 174**,** 113-121.

PRATT, B. & LOFF, B. 2011. Justice in international clinical research. *Dev World Bioeth,* 11**,** 75-81.

PRATT, B. & LOFF, B. 2013. Linking research to global health equity: the contribution of product development partnerships to access to medicines and research capacity building. *Am J Public Health,* 103**,** 1968-78.

PRATT, B. & LOFF, B. 2014. A Framework to Link International Clinical Research to the Promotion of Justice in Global Health. *Bioethics,* 28**,** 387-396.

PRATT, B., MERRITT, M. & HYDER, A. A. 2016b. Towards deep inclusion for equity-oriented health research priority-setting: A working model. *Soc Sci Med,* 151**,** 215-24.
PRATT, B., SHEEHAN, M., BARSDORF, N. & HYDER, A. A. 2018. Exploring the ethics of global health research priority-setting. *BMC Medical Ethics,* 19**,** 94.
QSR INTERNATIONAL 2018. NVivo qualitative data analysis Software. 12 ed.: QSR International Pty Ltd.
RAMOSE, M. B. 1999. *African Philosophy Through Ubuntu*.
RAMSAY, M. 2012. Africa: Continent of genome contrasts with implications for biomedical research and health. *FEBS Letters,* 586**,** 2813-2819.
RAMSAY, M., DE VRIES, J., SOODYALL, H., NORRIS, S. A. & SANKOH, O. 2014. Ethical issues in genomic research on the African continent: experiences and challenges to ethics review committees. *Human Genomics,* 8**,** 15.
RAPPERT, B. & BEZUIDENHOUT, L. 2017. Data sharing in low-resourced research environments. *Prometheus***,** 1-18.
RAWLS, J. 1971. *A Theory of Justice*, Harvard University Press.
RAWLS, J. 1985. Justice as Fairness: Political not Metaphysical. *Philosophy & Public Affairs,* 14**,** 223-251.
RAWLS, J. 1993. The Law of Peoples. *Critical Inquiry,* 20**,** 36-68.
ROSENBERG, N. A., HUANG, L., JEWETT, E. M., SZPIECH, Z. A., JANKOVIC, I. & BOEHNKE, M. 2010. Genome-wide association studies in diverse populations. *Nat Rev Genet,* 11**,** 356-66.
ROTIMI, C., LEPPERT, M., MATSUDA, I., ZENG, C., ZHANG, H., ADEBAMOWO, C., AJAYI, I., ANIAGWU, T., DIXON, M., FUKUSHIMA, Y., MACER, D., MARSHALL, P., NKWODIMMAH, C., PEIFFER, A., ROYAL, C., SUDA, E., ZHAO, H., WANG, V. O. & MCEWEN, J. 2007. Community engagement and informed consent in the International HapMap project. *Community Genet,* 10**,** 186-98.
ROTIMI, C. N., BENTLEY, A. R., DOUMATEY, A. P., CHEN, G., SHRINER, D. & ADEYEMO, A. 2017. The genomic landscape of African populations in health and disease. *Human molecular genetics,* 26**,** R225-R236.
ROTIMI, C. N. & JORDE, L. B. 2010. Ancestry and Disease in the Age of Genomic Medicine. *New England Journal of Medicine,* 363**,** 1551-1558.
RUGER, J. P. 2006. Toward a Theory of a Right to Health: Capability and Incompletely Theorized Agreements. *Yale journal of law & the humanities,* 18**,** 3-3.
RUGER, J. P. 2007. Global health governance and the World Bank. *Lancet,* 370**,** 1471-1474.
RUGER, J. P. 2008. Normative Foundations of Global Health Law. *The Georgetown law journal,* 96**,** 423-443.
RUGER, J. P. 2009. Global Health Justice. *Public Health Ethics,* 2**,** 261-275.
RUGER, J. P. 2010. Health capability: conceptualization and operationalization. *Am J Public Health,* 100**,** 41-9.
RUGER, J. P. 2011. Shared Health Governance. *The American Journal of Bioethics,* 11**,** 32-45.
RUGER, J. P. 2012a. Global health governance as shared health governance. *J Epidemiol Community Health,* 66**,** 653-61.
RUGER, J. P. 2012b. Global health governance as shared health governance. *Journal of Epidemiology and Community Health,* 66**,** 653.

RUGER, J. P. 2012c. Global Health Justice and Governance. *The American Journal of Bioethics,* 12**,** 35-54.
RUGER, J. P. 2013. Global Health Governance as Shared Health Governance. *In:* COHEN, G. I. (ed.) *The globalization of health care : legal and ethical issues.* Oxford: Oxford University Press.
RUGER, P. 2018. Shared Health Governace at the Domestic Level. *Global Health Justice and Governance.* Oxford: Oxford University Press.
SAMPAT, B. & WILLIAMS, H. L. 2019. How do patents affect follow-on innovation? Evidence from the human genome. *American Economic Review,* 109**,** 203-36.
SAMUEL, G. N. & FARSIDES, B. 2017. Genomics England's implementation of its public engagement strategy: Blurred boundaries between engagement for the United Kingdom's 100,000 Genomes project and the need for public support. *Public Understanding of Science,* 27**,** 352-364.
SANKOH, O. & IJSSELMUIDEN, C. 2011. Sharing research data to improve public health: a perspective from the global south. *The Lancet,* 378**,** 401-402.
SARGEANT, J. 2012. Qualitative Research Part II: Participants, Analysis, and Quality Assurance. *Journal of Graduate Medical Education,* 4**,** 1-3.
SASI 2017. San Code of Research Ethics. South Africa: South African San Institute
SCHROEDER, D. 2007. Benefit sharing: it's time for a definition. *Journal of Medical Ethics,* 33**,** 205-209.
SCHROEDER, D., LADIKAS, M., SCHUKLENK, U., DIÁZ, C. L. L., KLEINSMIDT, A., ALVAREZ-CASTILLO, F. & FEINHOLZ, D. 2005. Sharing the benefits of genetic research. *BMJ,* 331**,** 1351.
SCHROEDER, D. & LUCAS, J. C. 2013. Benefit Sharing: From Biodiversity to Human Genetics—An Introduction. *Benefit Sharing.* Springer.
SCHULZ-BALDES, A., VAYENA, E. & BILLER-ANDORNO, N. 2007. Sharing benefits in international health research. Research-capacity building as an example of an indirect collective benefit. *EMBO Reports,* 8**,** 8-13.
SEGAL, S. & HILL, A. V. 2003. Genetic susceptibility to infectious disease. *Trends in microbiology,* 11**,** 445-448.
SEGUIN, B., HARDY, B.-J., SINGER, P. A. & DAAR, A. S. 2008. Genomic medicine and developing countries: creating a room of their own. *Nat Rev Genet,* 9**,** 487-493.
SESAY, A. 2014. African Governance Systems in the Pre-and Post-Independence Periods: Enduring Lessons and Opportunities for Youth in Africa. Johannesburg: The Mandela Institute for Development Studies.
SETHI, N. 2018. Research and Global Health Emergencies: On the Essential Role of Best Practice. *Public health ethics,* 11**,** 237-250.
SHANYANANA, R. N. & WAGHID, Y. 2016. Reconceptualizing ubuntu as inclusion in African higher education: towards equalization of voice. *Knowledge Cultures,* 4**,** 104-120.
SHAPCOTT, R. 2011. Theories of Global Justice. *In:* BURKE, A., GEORGE, J. & DEVETAK, R. (eds.) *An Introduction to International Relations.* 2 ed. Cambridge: Cambridge University Press.
SHAPCOTT, R. 2014. International Ethics. *In:* BAYLIS, J., SMITH, S. & OWENS, P. (eds.) *The Globalization of World Politics: An introduction to International Relations.* Oxford: Oxford University Press.

SHAW, S., BOYNTON, P. M. & GREENHALGH, T. 2005. Research governance: where did it come from, what does it mean? *Journal of the Royal Society of Medicine,* 98**,** 496-502.
SIEGEL, A. W. 2008. Kantian Ethics, Exploitation and Multinational Clinical Trials. *In:* HAWKINS, J. & EMMANUEL, J. E. (eds.) *Exploitation and Developing Countries. Ethics of Clinical Trials.* Princeton, Oxford: Princeton University Press.
SINGER, P. A. & DAAR, A. S. 2001a. Harnessing Genomics and Biotechnology to Improve Global Health Equity. *Science,* 294**,** 87-89.
SINGER, P. A. & DAAR, A. S. 2001b. Harnessing genomics and biotechnology to improve global health equity. *Science,* 294**,** 87-9.
SLAUGHTER, A.-M. 2011. International relations, principal theories. *Max Planck encyclopedia of public international Law.*
SMITH, G. & WALES, C. 2000. Citizens' Juries and Deliberative Democracy. *Political Studies,* 48**,** 51-65.
SMITH, J. 2018. Parasitic and parachute research in global health. *The Lancet Global Health,* 6**,** e838.
SMITH, R. D., THORSTEINSDOTTIR, H., DAAR, A. S., GOLD, E. R. & SINGERS, P. A. 2004. Genomics knowledge and equity: a global public goods perspective of the patent system. *Bull World Health Organ,* 82**,** 385-9.
SRIDHAR, D. 2012. Who Sets the Global Health Research Agenda? The Challenge of Multi-Bi Financing. *PLOS Medicine,* 9**,** e1001312.
STAKE, R. E. 1995. *The Art of Case Study Research,* SAGE Publications.
STAPLETON, G., SCHRÖDER-BÄCK, P., LAASER, U., MEERSHOEK, A. & POPA, D. 2014. Global health ethics: an introduction to prominent theories and relevant topics. *Global Health Action,* 7**,** 23569.
STARMAN, A. B. 2013. The case study as a type of qualitative research. *Journal of Contemporary Educational Studies/Sodobna Pedagogika,* 64.
STAUNTON, C. & MOODLEY, K. 2013. Challenges in biobank governance in Sub-Saharan Africa. *BMC Medical Ethics,* 14**,** 35.
STAUNTON, C., TINDANA, P., HENDRICKS, M. & MOODLEY, K. 2018. Rules of engagement: perspectives on stakeholder engagement for genomic biobanking research in South Africa. *BMC Medical Ethics,* 19**,** 13.
STEVENSON, A., AKENA, D., STROUD, R. E., ATWOLI, L., CAMPBELL, M. M., CHIBNIK, L. B., KWOBAH, E., KARIUKI, S. M., MARTIN, A. R., DE MENIL, V., NEWTON, C. R. J. C., SIBEKO, G., STEIN, D. J., TEFERRA, S., ZINGELA, Z. & KOENEN, K. C. 2019. Neuropsychiatric Genetics of African Populations-Psychosis (NeuroGAP-Psychosis): a case-control study protocol and GWAS in Ethiopia, Kenya, South Africa and Uganda. *BMJ Open,* 9**,** e025469.
SULAMOYO, D. 2010. "I Am Because We Are": Ubuntu as a Cultural Strategy for OD and Change in Sub-Saharan Africa. *Organization Development Journal,* 28**,** 41-51.
TANGWA, G. B. 2017. Giving voice to African thought in medical research ethics. *Theoretical Medicine and Bioethics,* 38**,** 101-110.
TAUBER, A. I. 2002. Medicine, public health, and the ethics of rationing. *Perspect Biol Med,* 45**,** 16-30.
THE INTERNATIONAL HAPMAP CONSORTIUM 2003. The International HapMap Project. *Nature,* 426**,** 789-796.

THE MALARIA GENOMIC EPIDEMIOLOGY NETWORK 2008. A global network for investigating the genomic epidemiology of malaria. *Nature,* 456**,** 732-737.

TINDANA, P., BULL, S., AMENGA-ETEGO, L., DE VRIES, J., ABORIGO, R., KORAM, K., KWIATKOWSKI, D. & PARKER, M. 2012. Seeking consent to genetic and genomic research in a rural Ghanaian setting: A qualitative study of the MalariaGEN experience. *BMC Medical Ethics,* 13**,** 15.

TINDANA, P. & DE VRIES, J. 2016. Broad Consent for Genomic Research and Biobanking: Perspectives from Low- and Middle-Income Countries. *Annu Rev Genomics Hum Genet,* 17**,** 375-93.

TINDANA, P., MOLYNEUX, C. S., BULL, S. & PARKER, M. 2014. Ethical issues in the export, storage and reuse of human biological samples in biomedical research: perspectives of key stakeholders in Ghana and Kenya. *BMC Med Ethics,* 15**,** 76.

TOSAM , M. J. 2014. The Relevance of Kom Ethics to African Development. *International Journal of Philosophy. ,* 2**,** 36-47.

TOSAM, M. J., CHI, P. C., MUNUNG, N. S., O.O.M, O. B. & TANGWA, G. B. 2017. Global health inequalities and the need for solidarity: a view from the Global South. *Developing World Bioethics,* 0**,** 1-9.

TUKAI, A. 2018. Sex Workers Involved in HIV/AIDS Research. *In:* SCHROEDER, D., COOK, J., HIRSCH, F., FENET, S. & MUTHUSWAMY, V. (eds.) *Ethics Dumping: Case Studies from North-South Research Collaborations.* Cham: Springer International Publishing.

TUTU, D. 2012. *No future without forgiveness,* Random House.

UMOREN, R., JAMES, J. E. & LITZELMAN, D. K. 2012. Evidence of Reciprocity in Reports on International Partnerships. *Education Research International,* 2012**,** 7.

UNDP 1997. *Reconceptualising governance,* New York, United Nations Development Programme.

UNESCO 1997. Universal Declaration on the Human Genome and Human Rights United Nations Education and Scientific Council.

UNESCO 2009. Overcoming inequality: why governance matters. Paris: United Nations.

UPSHUR, R. E. G., LAVERY, J. V. & TINDANA, P. O. 2007. Taking tissue seriously means taking communities seriously. *BMC Medical Ethics,* 8**,** 11.

VAISMORADI, M., TURUNEN, H. & BONDAS, T. 2013. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nursing & Health Sciences,* 15**,** 398-405.

VALADEZ, J. 2018. *Deliberative Democracy, Political Legitimacy, And Self-determination In Multi-cultural Societies,* New Yaork, USA, Routledge.

VAN RINSUM, H. J. & TANGWA, G. B. 2004. Colony of genes, genes of the colony: diversity, difference and divide. *Third World Quarterly,* 25**,** 1031-1043.

VAN SCHALKWYK, G., DE VRIES, J. & MOODLEY, K. 2012. "It's for a good cause, isn't it?" - Exploring views of South African TB research participants on sample storage and re-use. *BMC Med Ethics,* 13**,** 19.

VARMUS, H. & SATCHER, D. 1997. Ethical Complexities of Conducting Research in Developing Countries. *New England Journal of Medicine,* 337**,** 1003-1005.

VENTER, E. 2004. The Notion of Ubuntu and Communalism in African Educational Discourse. *Studies in Philosophy and Education,* 23**,** 149-160.

VERHAREN, C. 2008. Comparing Oromo and ancient Egyptian philosophy. *Journal of Oromo Studies,* 15**,** 1-32.
VEZZANI, S. 2010. Preliminary Remarks on the Envisaged World Health Organization Pandemic Influenza Preparedness Framework for the Sharing of Viruses and Access to Vaccines and Other Benefits. *The Journal of World Intellectual Property,* 13**,** 675-696.
VIERGEVER, R. F., OLIFSON, S., GHAFFAR, A. & TERRY, R. F. 2010. A checklist for health research priority setting: nine common themes of good practice. *Health Research Policy and Systems,* 8**,** 36.
VINES, TIMOTHY H., ALBERT, ARIANNE Y. K., ANDREW, ROSE L., DÉBARRE, F., BOCK, DAN G., FRANKLIN, MICHELLE T., GILBERT, KIMBERLY J., MOORE, J.-S., RENAUT, S. & RENNISON, DIANA J. 2014. The Availability of Research Data Declines Rapidly with Article Age. *Current Biology,* 24**,** 94-97.
WALPORT, M. & BREST, P. 2011. Sharing research data to improve public health. *The Lancet,* 377**,** 537-539.
WEATHERALL, D., CLEGG, J. & KWIATKOWSKI, D. 1997. The role of genomics in studying genetic susceptibility to infectious disease. *Genome Research,* 7**,** 967-973.
WERTHEIMER, A. 1999. *Exploitation,* Princeton University Press.
WESTERHAUS, M. & CASTRO, A. 2006. How Do Intellectual Property Law and International Trade Agreements Affect Access to Antiretroviral Therapy? *PLOS Medicine,* 3**,** e332.
WHITE, M. T. 2007. A Right to Benefit from International Research: A New Approach to Capacity Building in Less-Developed Countries. *Accountability in Research,* 14**,** 73-92.
WHO 2002. Genomics and World Health: Report of the Advisory Committee on Health Research. Geneva: World Health Organization.
WIDDERSHOVEN, G., ABMA, T. & MOLEWIJK, B. 2009. Empirical ethics as dialogical practice. *Bioethics,* 23**,** 236-48.
WILKINSON, M. D., DUMONTIER, M., AALBERSBERG, I. J., APPLETON, G., AXTON, M., BAAK, A., BLOMBERG, N., BOITEN, J.-W., DA SILVA SANTOS, L. B., BOURNE, P. E., BOUWMAN, J., BROOKES, A. J., CLARK, T., CROSAS, M., DILLO, I., DUMON, O., EDMUNDS, S., EVELO, C. T., FINKERS, R., GONZALEZ-BELTRAN, A., GRAY, A. J. G., GROTH, P., GOBLE, C., GRETHE, J. S., HERINGA, J., 'T HOEN, P. A. C., HOOFT, R., KUHN, T., KOK, R., KOK, J., LUSHER, S. J., MARTONE, M. E., MONS, A., PACKER, A. L., PERSSON, B., ROCCA-SERRA, P., ROOS, M., VAN SCHAIK, R., SANSONE, S.-A., SCHULTES, E., SENGSTAG, T., SLATER, T., STRAWN, G., SWERTZ, M. A., THOMPSON, M., VAN DER LEI, J., VAN MULLIGEN, E., VELTEROP, J., WAAGMEESTER, A., WITTENBURG, P., WOLSTENCROFT, K., ZHAO, J. & MONS, B. 2016. The FAIR Guiding Principles for scientific data management and stewardship. *Scientific Data,* 3**,** 160018.
WILLIAMS, H. L. 2010. Intellectual property rights and innovation: Evidence from the human genome. *The journal of political economy,* 121**,** 1-27.
WINICKOFF, D. E. 2008. From benefit sharing to power sharing: partnership governance in population genomics research.
WINICKOFF, D. E. & WINICKOFF, R. N. 2003. The Charitable Trust as a Model for Genomic Biobanks. *New England Journal of Medicine,* 349**,** 1180-1184.
WIREDU, K. 2000. Democracy and Consensus in African Traditional Politics: A Plea for a Non-party Polity *Polylog,* 2.

WIREDU, K. 2002. The moral foundations of an African culture. *In:* COETZEE, P. H. & ROUX, A. P. J. (eds.) *Philosophy From Africa: A Text with Readings.* Oxford University Press.
WIREDU, K. 2006. *A Companion to African Philosophy,* Oxford, Blackwell Publishing Limited.
WOLFFERS, I., ADJEI, S. & VAN DER DRIFT, R. 1998. Health research in the tropics. *The Lancet,* 351**,** 1652-1654.
WONKAM, A., KENFACK, M. A., MUNA, W. F. & OUWE-MISSI-OUKEM-BOYER, O. 2011. Ethics of human genetic studies in sub-saharan Africa: the case of Cameroon through a bibliometric analysis. *Dev World Bioeth,* 11**,** 120-7.
WONKAM, A. & MAYOSI, B. M. 2014. Genomic medicine in Africa: promise, problems and prospects. *Genome Medicine,* 6**,** 11.
WOOD, A. W. 2009. Exploitation. *Social Philosophy and Policy,* 12**,** 136-158.
WRIGHT, G. E., KOORNHOF, P. G., ADEYEMO, A. A. & TIFFIN, N. 2013. Ethical and legal implications of whole genome and whole exome sequencing in African populations. *BMC Med Ethics,* 14**,** 21.
YAKUBU, A., TINDANA, P., MATIMBA, A., LITTLER, K., MUNUNG, N. S., MADDEN, E., STAUNTON, C. & DE VRIES, J. 2018. Model framework for governance of genomic research and biobanking in Africa - a content description [version 1; referees: awaiting peer review]. . *AAS Open Res,* 1.
YASSIN, R., LOCKHART, N., RIEGO, M. G. D., PITT, K., THOMAS, J. W., WEISS, L. & COMPTON, C. 2010. Custodianship as an Ethical Framework for Biospecimen-Based Research. *Cancer epidemiology, biomarkers & prevention : a publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology,* 19**,** 1012-1015.
YIN, R. K. 2003. *Case Study Research: Design and Methods,* Thousand Oaks, SAGE Publications.
YOUNG, I. M. 2001. Activist Challenges to Deliberative Democracy. *Political Theory,* 29**,** 670-690.
YOUNG, I. M. 2002. *Inclusion and Democracy,* Oxford University Press.
ZAWATI, M. H., KNOPPERS, B. & THOROGOOD, A. 2014. Population biobanking and international collaboration. *Pathobiology,* 81**,** 276-85.

Appendices

Appendix 1: Research Ethics Clearance

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

04 August 2016

HREC REF: 548/2016

Dr J de Vries
Clinical Research Centre
J-52-16
OMB

Dear Dr de Vries

PROJECT TITLE: GOVERNANCE FOR GENOMICS RESEARCH AND BIOBANKING IN AFRICA: ETHICS AND REGULATORY ISSUES (PhD-candidate-N Munung)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 August 2017.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the student, N Munung will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 548/2016

Appendix 2: Informed Consent Form

Informed consent form (Expert interviews)

Title of Study: Governance for Biobanking and Genomics Research in Africa: Ethics and Regulatory Issues

Introduction

We invite you to take part in a research study that aims at investigating how genomics and bio-banking research in Africa could be governed to achieve fairness and foster justice. This study is part of a PhD in Medicine at the Department of Medicine, University of Cape Town. It is not an audit or trial. This form explains the research study. Please, read it carefully and ask any questions about the study before you agree to join. You may also ask questions at any time after joining the study.

Objective

The main objective of this study is to investigate how genomics and bio-banking research in Africa could be governed to achieve fairness and foster justice. This could generate empirical data that would inform ongoing discussions on key elements that should be incorporated in a good governance framework for bio-banking and genomics research in Africa.

The Researchers

This is a PhD research project executed by Nchangwi Syntia Munung, based at the Department of Medicine, University of Cape Town. It is supervised by Dr. Jantina de Vries at the University of Cape Town, South Africa.

Participants

Participants for this study will be people who have played a leading role in the development or application of governance mechanisms for genomics research and biobanking in Africa. This could include, for instance: senior researchers involved in genomics research in Africa, bioethicist, members of regulatory authorities, research ethics committee members, biobank operators, policy makers and funders. We anticipate to include no more than 30 people in this study.

Research Procedure

If you agree to participate, we will discuss with you what you consider to be key elements for a fair governance framework for collaborative African genomics and biobanking research in Africa. Interviews will amongst others focus on governance of access to and secondary use of samples, control of data ownership/custodianship of samples and benefit sharing.

The interview will be conducted via telephone or Skype or at a location of your choice. The conversation will last approximately one hour. It will be audio recorded. The recordings will be transcribed after which they will be destroyed. At the end of this project, all sources of potential

identification will be removed from the transcripts and the transcripts may be deposited in an archive. The interview will be done in English or French.

Confidentiality
We will keep what you have said to us private. When we write the discussion down, it will not have your name on it but a code. The information collected will be kept in restricted access offices and on password-secured computers. We will not publish entire interviews, but it is important that you understand that excerpts may be used to report on this study, for instance in the thesis or publications. If this is done, a piece of text from your interview will appear together with a code (for example, 'IDI1'). If we deposit the transcripts in an archive, we will make sure that any information that could identify you is removed.

Voluntariness and right to withdraw
Your participation in this research project is voluntary. If during the interview or at a later date you have second thoughts, then please feel free to withdraw from the study. We can terminate the interview at any time, and the recording will be destroyed.

Risks/Discomforts
There are no physical risks in this study. However, you might feel upset or worried to when answering some of the questions. To minimize this, please, feel free to choose not to answer any questions you do not want to.

Anticipated Benefits
If you decide to participate in this study, you will receive no direct benefit. However, your contribution will inform ongoing discussions on appropriate governance mechanisms for genomics research and biobanking in Africa.

Compensation
You will not receive any compensation for participating in this study.

Contact Information
If you would like more information about this research project before/after deciding to participate, please contact Nchangwi Syntia on mobile phone (+27)604227239 or by email (MNNNCH001@myuct.ac.za). You could also contact Dr Jantina de Vries at (+27) 021 650 5716 or by email (jantina.devries@uct.ac.za). If you think you have not been treated fairly or have been hurt by joining this study, please contact the Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town on 021 406 6338 or write to Shuretta Thomas, Human Research Ethics Committee, Room E52-24, Old Main Building, Groote Schuur Hospital, Observatory 7925, Cape Town.

Consent Form

Title of Study: Governance for Biobanking and Genomics Research in Africa: Ethics and Regulatory Issues

Have you been provided with sufficient information about the study? Yes ☐ No ☐

Have you had an opportunity to ask questions and discuss this study? Yes ☐ No ☐

Have you received satisfactory answers to all your questions? Yes ☐ No ☐

Do you understand that your participation is voluntary, and that you are free to withdraw from the study at any time? Yes ☐ No ☐

Do you agree to take part in this study? Yes ☐ No ☐

Signature……Date……

Name in block letters ……

Investigator's Statement

I confirm that I have carefully explained the proposed study to the participant.

Signature……Date……

Name ……

Appendix 3: Interview Guide (Pool of questions)

1 **Interview Guide-Governance of GR&B in Africa**

Process (H3Africa Ethics and governance framework)

1. You were involved in the development of the H3Africa governance framework and attended the meeting in Stellenbosch. Why was there a need to develop a framework and not, for example, use that developed by other international initiatives?

2. That meeting had involved different stakeholders. Do you feel that you had an equal opportunity relative to other participants to share your views during the process?"

3. Do you feel that all participants had an equal opportunity relative to other participants to share their views during the process? If not, who had less opportunity and why?"

4. In terms of the final version of the framework, do you feel that all participants had an equal opportunity relative to other participants to be heard and to influence decision-making? If not, who had less opportunity? What could have been done differently?

5. Do you feel that you had an equal opportunity relative to other participants to be heard and influence decision-making during the process

6. What group of stakeholders were missing from the process who, in your opinion, should ideally have been included? Why is it important to include this stakeholder group?

Principles

1. What principles and values, would you say, are key in promoting justice and fairness in genomics research and biobanking in Africa

2. In the development of the ethics and governance framework, you had expressed deep interest in interest using Ubuntu as a guiding moral theory for establishing governance for genomics and biobanking in Africa.

    a. What values or principles of Ubuntu, do you think, will be important in governance of genomics and biobanking? Why?

    b. How would those principles and values promote fairness and justice in genomics research and biobanking in Africa?

3. What other African values do you think should be incorporated in ethics and governance frameworks for genomics and biobanking in Africa: Why: how would it promote justice and fairness?

4. Transparency and accountability are generally considered key principles for good governance. How could both principles be achieved in genomics in genomics research and biobanking consortia in Africa and in data sharing specifically?

Access to samples and Data

a. How can access to data and samples be done such that is benefit to African researchers and populations?

b. What would be a best approach to regulating access to data and samples such that it is of benefit to African researchers and research participants?

c. Access to data and samples will be decided by a DBAC. What, in your opinion, should be the composition of the DBAC such that it promotes fairness and equity?

d. How can fairness be effectively promoted during decision making on access to samples and data

e. There is an embargo period of 12 months, which allows for African primary researchers to publish their studies before data can be shared. How does this promote fairness and justice?

f. What could be done to make sure that African researchers and populations benefit from secondary use of data and samples collected as part of African genomic projects?

g. Do you feel there is a need to monitor data and sample sharing activities in genomics research and biobanking consortia in Africa? Why? How can it be done?

Benefit Sharing

Benefit sharing remains a controversial issue in genomics research and biobanking? What will be the best way of addressing questions of benefit sharing?

Ownership of data and samples:

- There are concerns around ownership of data and samples. How could this be possibly addressed within the consortium

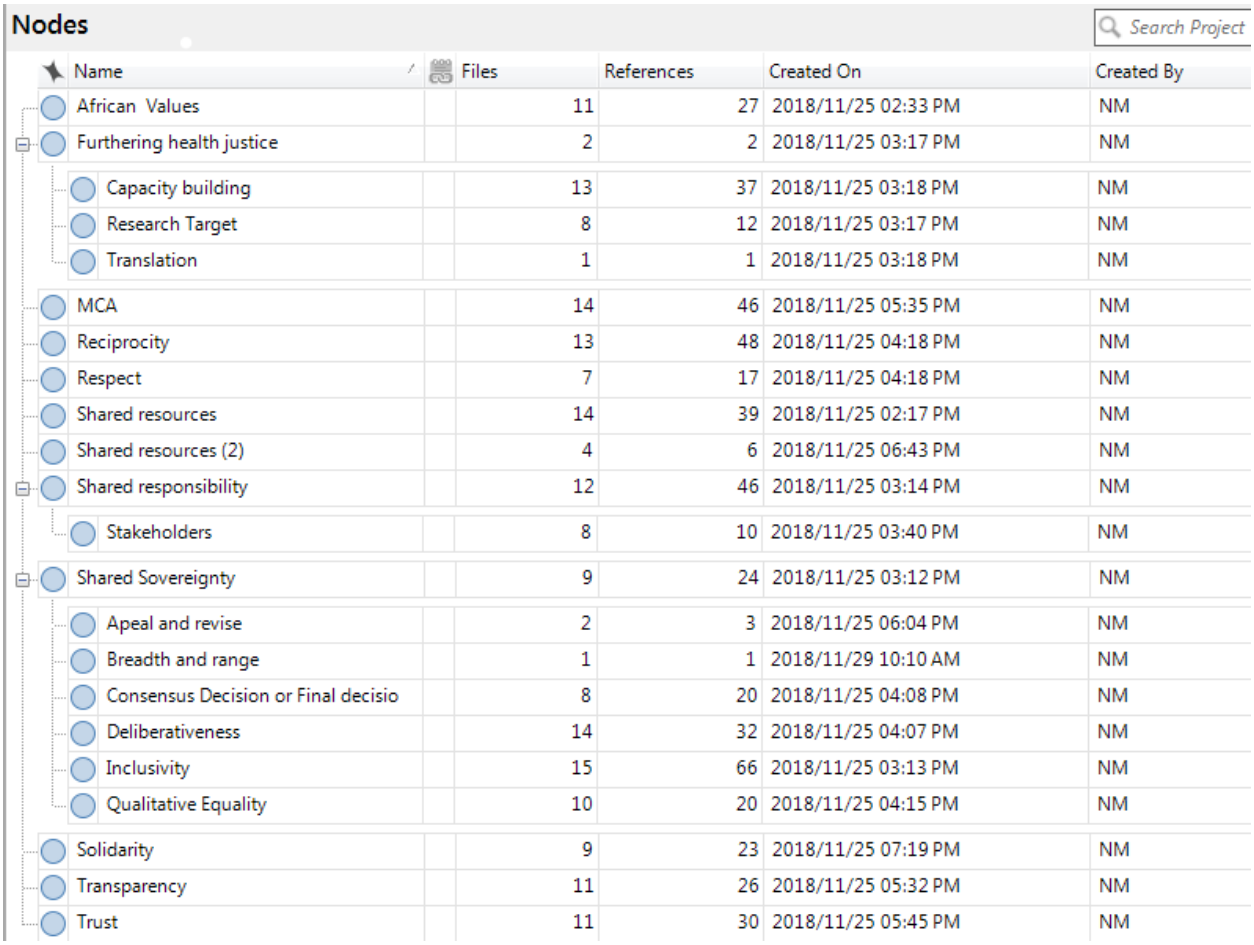
- What should be the guiding principles and values

Responsibility of Stakeholders

- What would you suggest as a list of stakeholders in genomics and research and biobanking in Africa? What should be the responsibility of each stakeholder?

- What would you say are the responsibility of the data producers, users and funders in genomics consortia that plan to share data

Appendix 4: NVivo Screenshot showing different codes



Nodes

Search Project

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Furthering health justice	2	2	2018/11/25 03:17 PM	NM
Capacity building	13	37	2018/11/25 03:18 PM	NM
Research Target	8	12	2018/11/25 03:17 PM	NM
Translation	1	1	2018/11/25 03:18 PM	NM
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Reciprocity	13	48	2018/11/25 04:18 PM	NM
Respect	7	17	2018/11/25 04:18 PM	NM
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Inclusivity	15	66	2018/11/25 03:13 PM	NM
Qualitative Equality	10	20	2018/11/25 04:15 PM	NM
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