DEPARTMENT OF POPULATION, FAMILY AND REPRODUCTIVE HEALTH

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ETHICAL ASPECTS OF GENOMICS DATA SHARING WITH COMMERCIAL ENTITIES: A CASE STUDY OF THE AWIGEN COLLABORATIVE SATELLITE PROJECT IN KENYA

BY

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DECLARATION

I, James Waweru, hereby declare that except for other people's work, which I have duly acknowledged, this thesis is the result of my original research conducted under the supervision of Prof. Paulina Tindana. I further declare that this thesis, either in whole or in part, has not been submitted elsewhere for another degree.

James Waweru ..... 28th December 2024

(STUDENT ID: 10932368) (Signature) **(Date)**

Prof. Paulina Tindana ..... 28th December 2024

(Supervisor) (Signature) (Date)

DEDICATION

I acknowledge my family for their thoughtful insights throughout the course. The dissertation was supported by the H3Africa CEBioGen Project Team at the University of Ghana through the Department of Population, Family, and Reproductive Health School of Public Health. I dedicate this dissertation to community members and researchers in the heart of Nairobi. Their reception to science and the steps they take towards science bettering lives is encouraging. The Community Health Workers and Community Members are at our hearts when researching.

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ABSTRACT

Background: In the past decade, there has been an exponential growth in genomic research in Africa. While these studies have contributed to building scientific capacity on the continent, they have also raised pertinent ethical issues. One of the key genomic initiatives is the Human Heredity and Health in Africa Initiative which has conducted genomics studies across several countries in Africa. During the implementation of the H3Africa AWI-Gen project, one of the key ethical concerns identified was data sharing, particularly with commercial companies. While there is growing interest on this topic, no study has been conducted to explore the perspectives of key stakeholders on the ethical aspects of data sharing with commercial entities on the African continent. Therefore, this study aimed to address this gap using one of the H3Africa collaborative projects – the AWIGen Collaborative project - as a case study.

Methods: The research employed an exploratory qualitative case study methodology, which involved observations, in-depth interviews and focus group discussions with key research stakeholders. The primary focus of this study was on individuals residing in Kenya, namely in the informal urban settlements of Korogocho and Viwandani in Nairobi. The study aimed to include a specific sample population consisting of adults aged 45-60 who had prior involvement with a genomic study (the H3Africa AWI-Gen Project), as well as the project staff. The interviews explored participants' views on policies, laws, and regulations pertaining to the sharing of data with commercial entities, as well as ethical concerns that need to be addressed to promote good ethical practices in data sharing.

Results: The study highlighted a general support in genomic data sharing with commercial entities with a specific inclination to benefit sharing or transfer of health benefits to the populace. However, participants also raised concerns around the safety of the blood drawn for tests and its implications. Further, the sample population exhibited hesitance to provide biodata for the wrong usage by data

collectors in the future. However, the researchers involved with AWI-Gen were skeptical about sharing genomic data with commercial entities, pointing out the need for diverse protection of participant data. Researchers also reported that the policies that were locally enforced in sharing general biodata and genomic data, such as the Kenyan Data Protection Act 2019, have demonstrated the need for policy and the advancement of ethical understanding surrounding Public Health Data. They recommended that data managers, collectors, and handlers should integrate these policies using identifiers or anonymous data processing and analysis.

Conclusion: Local communities participating in genomics research are generally in support of data-sharing with commercial entities. However, they expect medical benefits from the data-sharing practices with commercial entities, especially in disease management and prevention. There is the need for research institutions and commercial entities to collaborate to extend research benefits and other socio-economic advantages to communities where the data were collected.

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OPERATIONAL DEFINITIONS

Data Sharing: is the practice of sharing data generated from genetics and genomics research with researchers who were not originally part of the project.

Commercial entities: This refers to a legal organization that engages in commercial activities. Within the context of genomics research, this will include pharmaceutical companies.

Low and Middle-Income Countries; are a diverse group of countries categorized by diverse group size, population, and income level. The economies in such countries are between GNI (per annum) of $1,036 and $4,045. These countries are home to 75% of the world's population and 62% of the world's poor. They serve as global engines of industry in consumption and labor resource.

Industry Led Research (ILR); is a research strategy steered by the industries involved.

Patient Led Research (PLR); these are research strategies steered by tail-end users of persons participating in offering material and data for research purposes.

Narrative Ethics Techniques; these are techniques that build on moral standings from oral or written narratives derived from communities, especially on unexplored phenomena.

Broad Consent; refers to consenting techniques that branch out to various data collected for research purposes from one project.

Re-consenting; the act of seeking a formerly involved participant of a research project to consent to new developments emanating from their research data or research material.

Data set Distinction: the differentiation of the three different data sets collected from the genomic research of AWI-GEN, namely; genomic data, bio data from measurements, and verbal interview data.

Fair Data Set Distinction*:* the differentiation of two data sets by interviewees from the AWI-Gen project, of which one was genomic data.

Low Data Set Distinction: the differentiation of one or two data sets from the AWI-Gen data

collection with none of the two data sets being genomic data.

High Data Set Distinction: the differentiation of three data sets by participants in the AWI-Gen Project whereby genomic data was included.

LIST OF ABBREVIATIONS

CE-BioGen	Community Engagement in Bio-banking and Genomics
AWI-Gen	Africa Wits-IN-DEPTH Partner-ship for Genomic Research
HDSS	Health Demographic Surveillance System)
ESRC	Ethics Scientific Review Committee
APHRC	African Population Health and Research Center
GWAS	Genome-Wide Association Studies
H3Africa	Human, Heredity & Health Africa Research
IRB	Independent Review Board
DPA	Data Protection Act

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CHAPTER ONE

INTRODUCTION

1.1. Introduction

Globally, there has been a growing establishment of genomic databanks that collect human specimens for research. Collections of genomic data promote indigenous research and are shared with commercial entities for additional community benefits through health programmes

. Africa has seen a rise in genomic studies through platforms facilitating these essential research activities to improve genomic knowledge and capacity (Knoppers & Joly, 2018). Genomic research incorporates regulatory frameworks and ethical observations which have narrowed data-sharing practices for the benefit of communities. Genomic data-sharing regulations focus on protecting research participants' information from being used in harmful ways and to increase the involvement of the health frontier towards advancing knowledge in communicable and non-communicable diseases (Jiang & Tang, 2020).

In the past decade, the Human Heredity and Health in Africa (H3Africa) consortium (Rotimi et al 2012), has conducted several genomic studies across the Africa continent. One of the collaborative projects under this consortium - The Africa Wits INDEPTH Partnership for Genomic Research (AWI-Gen) - has been at the center of genomic studies leveraging health consequences of genomic influences of environmental and lifestyle factors (Asiki et. al. 2018). The target population for the AWI-Gen study was individuals aged 40-60 in four countries; Kenya, Burkina Faso, South Africa, and Ghana. In Kenya, the AWI-Gen study focused on the informal urban communities of Korogocho and Viwandani, which formed part of the sample population. Notably, these households were part of the Nairobi Urban Health and Demographic Surveillance System

(NUHDSS). Communities actively engaged in these projects are more adept to societal changes that can affect ethical perspectives. African Population Health and Research Center (APHRC) researchers researched on behalf of the H3Africa AWI-Gen project in Kenya and provided training, infrastructure, and ethical guidelines necessary for the research.

Various data types were collected from the participants during the AWI-Gen project, prompting data-sharing governance within the institutions involved. These data include biodata, genomic data, and survey data. The data pooling process places the participants at risk of privacy infringements and exploitation attempts unforeseeable in the future. However, data pools have low risks of privacy infringements by implementing genomic data sharing practices that are well regulated to encompass private equity companies involved in healthcare information and technological strategies. As a result, participants' safety is more assured through data-sharing policies that mitigate the misuse of the data due to the growing data aggregation and fusion in various research firms (Sisk & Kodish, 2018).

1.2 Problem Statement

Following the completion of the human genome project in 2003, several genomic studies have been conducted across the globe. In Africa, the growth of genomic research started slowly with initiatives such as the MalariaGen Consortium (Tindana et al 2012). Then, in 2012, the Human Heredity and Health in Africa Initiative (H3Africa) was launched - with funding from the United States National Institutes of Health (NIH) and the Wellcome Trust – to strengthen genomic capacity on the African continent and to support the implementation of research projects to address infectious and non-communicable diseases affecting African populations.

The Consortium comprises 51 African projects encompassing population-based genomic research on prevalent non-communicable diseases like heart and renal disease, along with communicable diseases such as malaria and tuberculosis. Led by African scientists, these studies are conducted collaboratively for the African population. They employ a range of methods, including genetic, clinical, and epidemiological approaches, to investigate both hereditary and environmental factors contributing to health and disease (H3Africa report 2022). Since then, Africa has witnessed a tremendous growth in genomic studies which has supported scientific capacity building in infrastructure and human capacity as well as the development of research protocols and ethics guidelines. Considering the extensive genetic diversity within African populations, H3Africa serves as an exceptional research asset, aiming to benefit individuals in Africa and worldwide. Consequently, data sharing is a fundamental principle guiding H3Africa, and aligns with its mission to translate research findings into commercial products, resources, and services (H3Africa report, 2022). While these studies have also contributed to genomic sequencing capacities and our understanding of the interactions between human genes and the environment, they have also raised pertinent ethical concerns including data and sample sharing with commercial entities (DeVries et al 2015; Tindana et al 2017; Schultz B et al 2023; H3Africa report, 2022).

Also, despite the scientific rationale supporting the sharing of genomics data with commercial entities, the topic remains controversial due to the association of the term "commercialization" with profit-making and potential exploitation of research participants. Anecdotal reports from the implementation of the H3Africa projects suggest that data sharing with commercial companies may face ethical challenges without clear benefit-sharing plans. The use of local lingo further complicates discussions around commercialization. Following reports on the purported

unauthorized utilization of DNA samples from hundreds of African individuals for the development of a DNA chip (Stokstad, E. 2019), there have been renewed discussions on the interpretations, consequences, and effects of commercialization, benefit sharing, and proper consent within the realm of genetics and genomics research (H3Africa Report, 2022). These incidents also prompted introspection within the field, drawing increased attention to the protocols and procedures governing the consent of participants in large-scale global projects that may result in the creation of commercial resources or products. The H3Africa Report on Informed Consent and Commercialization (H3Africa 2021) proposes the adoption of a standardized terminology for concepts like selling and profiting in commercialization. It also suggests explicit statements in consent forms to clarify that researchers are not selling human samples for profit and cautions against using the term 'commercialization' vaguely in communications with communities and participants.

Additionally, the report calls for community engagement processes to include discussions on commercialization and advocates for more empirical research to explore stakeholders' perspectives. Given the lack of evidence on how various stakeholders, including research teams and participants, perceive the sharing of data with commercial companies like Big Pharma, this study aims to address this recommendation by examination of perspectives of research participants, research staff, and other key stakeholders on the ethical dimensions of data sharing with commercial entities. An introspective study to explore these perspectives would be valuable in shaping guidelines and policies for responsible and equitable data sharing with commercial entities.

1.3 Research Questions.

- What are the ethical aspects of genomic data-sharing practices between researchers and commercial entities?
- How should research stakeholders improve data confidentiality while sharing genomic data?
- What policies should be implemented to improve the goodwill of commercial healthcare entities to communities when genomic data is shared?

1.3.1 General Objective

The study aims to explore the perspectives of key stakeholders on the ethical aspects in data sharing with commercial entities in the context of genomics research in Kenya.

1.3.2. Specific objectives

- To explore key stakeholders' perspectives for or against genomic data-sharing practices between research stakeholders and commercial entities.
- To assess stakeholder's perspectives to build the narratives motivating various aspects of Genomic Data sharing.
- To examine the processes involved in protecting data confidentiality while sharing genomic data.
- To examine implementable policies that promote the ethical practice of data sharing with commercial entities.

1.5 Study Justification

Ethical considerations are paramount in research involving human subjects. Recent controversies and concerns surrounding unauthorized use of genetic data have underscored the necessity to thoroughly investigate the ethical implications of data sharing with commercial entities (Stoktad E 2019; H3Africa Report, 2022). The proposed study is therefore a response to recommendations made by the H3Africa consortium for more empirical evidence and insights into thesecontroversies, and thus fosters a deeper understanding of the associated challenges. Also, investigating the ethical dimensions of data sharing will ensure that the rights and interests of participants are safeguarded, especially when collaborating with commercial entities. This aligns with the ethical principle of respect for persons and participant autonomy which boosts sustainable research practices.

Given the lack of clear guidelines and policies on what should constitute good ethical practices when sharing data with commercial entities, the study aimed to contribute valuable information for the development and refinement of policies governing data sharing practices. Identifying ethical issues can inform the development of guidelines that balance the advancement of research with the protection of participant welfare.

Research transparency is essential in maintaining public trust in scientific research and enhancing trust among research participants, the wider public, and commercial entities involved. By systematically exploring ethical issues through the perspectives of key stakeholders, this proposed study could potentially contribute to the transparency of data-sharing practices. Understanding the ethical considerations in data sharing with commercial entities is crucial for maximizing the socio-economic impact of research. The study can identify ways to ensure that benefits derived from commercialization efforts are ethically distributed, contributing positively to communities involved.

Findings from this research can serve as a guide for researchers, practitioners, and policymakers involved in data sharing and the insights can inform best practices, ethical decision-making, and the development of protocols that foster responsible and equitable sharing of data in genomic research and bio-banking in Africa.

1.6. Thesis outline

This dissertation is structured into six (6) main chapters. This first chapter describes the background information on the study, the problem statement, research questions, and research objectives, as well as the justification for the study. Chapter two presents a synthesis of current literature on the research topic. Chapter three describes the study design, location, population, and methods. Chapter four presents the key results of the research. Chapter five discusses the study's results concerning existing literature, and finally, Chapter Six presents the study's main conclusions and key recommendations.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

This chapter presents a synthesis of the literature on genomic studies in Africa, the AWI-Gen & H3Africa project, and the various policies guiding the ethical sharing of genomic data. The chapter ends with a summary of gaps in knowledge.

2.2 Genomics Research in Africa before African Genomic Studies.

Africa has been recognized as the original location of all modern humans, though the characterizations of the genetic variations across sub-populations in the continent have been burdensome. Early genomic studies in Africa were able to categorize 14 African ancestral population clusters (Tishkoff et al., 2009). There is shared ancestry within the population alluding to the fact that there could be migration events and mixtures of linguistic properties. The modern humans have been existing continuously in Africa longer than in any other region. Africa contains more than 2000 distinct ethno-linguistic groups accounting for a third of the world's languages (Tishkoff et al., 2009).

The genomic variation studies conducted before the human genome project observed the differentiation of the African populations caused by ethnicity, language, geography, technological shifts and climatic shifts. The factors of genomic variations contributed to the fluctuations, fragmentation and dispersal of populations of African indigenous people all across Africa. The association of genetic and geographic distance is highly considered in genomic research since the genomes of Africans vary in relation to their distance from each other (Dries, 2009). This could be contributed to by climatic differences and different modes of life for

different communities. The cases that were intriguing for researchers in African Genome Variation Projects (AGVP) were those of African tribes that had genetic introgression while maintaining their deep cultural lifestyles like the Maasais of Kenya (Tishkoff et al., 2009). The study of genetic make-up against the ethnic and community backdrop is a marvel and an induction of data. Genomic data coupled with ethics and communal narratives assist to build ethical and moral philosophy in the utility of data as a bioethical initiative. The African population is extensively diverse and projects should aim to be inclusive of populations that are left out in contemporary studies. Genomic studies in Africa for example could intimate re-sequencing, genome wide association (GWAS) and pharmacological studies to identify gaps in research populations within Africa.

2.3 The Human Heredity and Health in African Initiative

In June 2010, the National Institute of Health and Wellcome Trust announced a partnership backed by the first-round award of $40 million as a fund for selective genomic research in African countries (Adoga et al., 2014). This partnership led to the H3Africa project, which sought to strengthen the capacity of African scientists to conduct genomics studies on the continent. In one of its forums, Dr. Eric D. Green of the National Human Genome Research Institute (NHGRI) stated that the consortium intended to demonstrate continued commitment to furthering the capacity for research in Africa (National Human Genome Research Institute: 2014). The research support is proven by H3Africa's engagement in research projects, capacity building, and community engagements meant to advance the health of populations within Africa.

The H3Africa Consortium facilitates research into diseases prevalent in Africa by providing and

developing infrastructure, resources, training, and ethical guidelines. H3Africa provides unparalleled research resources in line with the vast genetic diversity with an interest of benefiting the African people (Marshall et al., 2022). The H3Africa initiative happened under the collaboration of the National Institute of Health through allocated funding. As a pioneer institution inherently involved in genomic data collection, processing, and analysis, data-sharing practices form the backbone of its activities. The focus is to equip, empower and train African scientists on elements of capacity building on ethical, legal, and social implications of research regarding bioinformatics, bio-banking, and networking (Adoga et al., 2014). As an institution, the initiative denotes that Africa holds a diverse genomic database compared to other global regions. The institution's role in genomic studies aligns with the growing need to identify and present the undocumented variants that are helpful to the global population. Data sharing is at the core of the H3Africa activities whereby the information has great value in enhancing knowledge, while still aiming to benefit communities (Marshall et al., 2022).

Stakeholders in research should be at the forefront of protecting the participants' interest in the research data. There has been an exploitation of genomic data from participants in the past that should foresee institutions implementing proactive measures that promote the emergence of facilitative data-sharing experiences rather than postpone the topic altogether leading to unethical interactions in data use (Holden, 2009). H3Africa represents has built a sustainable genomic research culture akin to developing fair and just data governance frameworks on informed `consenting, ethical oversight, and sample re-use conditions.

Figure 1: H3Africa Consortium Constitutive Representation

Source: (H3Africa, 2023)

2.3.1. The H3Africa Wits-INDEPTH Collaborative Genomics Projects (AWI-Gen)

The Africa Wits-INDEPTH partnership for Genomic Studies (AWI-Gen) is a center of the Human Heredity and Health in Africa (H3Africa) consortium operating under the NIH (National Institute of Health) fund. The research projects are undertaken by a strategic partnership between the University of Witwatersrand, Johannesburg (Wits), and the International Network for the Demographic Evaluation of Populations and Their Health (INDEPTH), with complimentary efforts from each partner.

The center made use of integrated health survey systems in the respective countries involved through Health and Demographic Surveillance Systems (HDSS) centers and the Developmental Pathways for Health Research Unit (DPHRU). These surveillance systems were incorporating longitudinal cohorts in the urban (Soweto and Nairobi) and rural areas of (Navrongo, Naonoro, Agincourt and Dikgale). The systems provided long conducive and sustainable research environments through community engagement, trained personnel and demographic phenotypic data focused on communities grappling with cardio metabolic health and obesity. The University of Witwatersrand has been involved with population genetics and genome wide association studies (GWAS) under the AWI-Gen project.

The AWI-Gen research project had three main objectives in its impact. The objectives were as follows:

(1) Capacity building to provide and enhance skills required in genomic research. The centers have had the ability to perform data collection and management, epidemiology and biostatical analyses, though none was initially involved in genomic research before AWI-Gen. (2) Provide structural genetic architecture within the population (Dandara, 2014). The genetic make-up comprising of phenotypes and genotypes could be mapped geographically and historically in some urban and rural settings, and this could be used to inform analysis prior to research being carried out. (3) To investigate the interacting and independent genomic factors that are related with both behavioral and environmental opportunities.

2.3.2. Community Engagement in Biobanking and Genomics Collaborative Project (CEBioGen)

The collaborative center of Community Engagement in Biobanking and Genomics (CEBioGen) was established to provide evidence-based strategies that prove effective community engagement for genomics and biobanking.

The center carried out Community Engagement in four countries that were having three inter-related projects including the AWI-Gen project. The countries involved were Ghana, Kenya, Nigeria and South Africa. One of the project's aims was to explore the innovative and impactful ways in which aggregate results could be shared back to participants involved with the H3Africa AWI-Gen project in Ghana, Kenya and South Africa. One of the key issues that emerged in the course of implementing the CEBioGen project was whether it is acceptable to share data with commercial companies and what should count as good ethical practice to promote responsible and ethical data sharing. This current study is therefore embedded in the CEBioGen project and sought to understand the ethical aspects of data sharing with commercial entities and how genomics research can benefit local communities participating in these studies

2.4 Ethical issues in genomics research in Africa

Cultural beliefs and practices leading to ethical issues affect genomic research in Africa. Ramsey et al. (2014) have suggested that ethical concerns in genomic studies are linked to lack of effective community engagement, risks of stigmatization, and data-sharing practices. Research in the communities should render benefits guided by the ethical narratives and policies of the community. Chokshi et al. (2006) identifies an emphasis on ethical regulations in data utility and biological samples, but this strategy alone would lead to less potent and incomprehensible research data. Over the past decade, several ethical issues such as consent, data and sample sharing, benefit-sharing and community engagement have emerged as pertinent to the conduct of genomics research in Africa.

From ethical philosophers in the region it is argued that African traditional healers were not geared towards profit making. Ethicists such as Tangwa (2010), have debated Big Pharma being about profit making while Africa is not profit geared in situational ailments especially in communitarian societies. The ethics of Western countries has not integrated other cultures that are not of its own. This has brought about the imperialism of health services whereby the control and manipulation of data is done by few players enjoying political advantage and pro-colonial influences. The pro-individualistic ethics is not widely celebrated in Africa as Communitarian benefits as expressed by ethicists such as Gyekye (1997) who argues that African culture values both the community and the individual. The communitarian approach to ethics has been explored by other Afri-ethicists such as Adeate, (2023) who was a proponent for moderately incorporating communitarianism in Research and bioethics in line with African cultural practices.

Over the past decade, several ethical issues such as consent, data and sample sharing, benefit-sharing and community engagement have emerged as pertinent to the conduct of genomics research in Africa.

2.4.1. Seeking Consent for genomics and biobanking

Seeking valid informed consent from research participants has been one of the contentious issues in research ethics in general and unsurprisingly it remains one of the most debated issues in the context of genomics research globally (Tindana et al 2007, Tindana et al 2012, Munung, et al. 2015; Tindana et al 2020). The nature of genomics research requires that participants consent to the future use of their human biological samples and associated data, beyond the primary research they are being asked to participate it.

This raises concerns about the validity of consent and whether consenting to future 'unknown research' could be said to be truly informed. Given these complexities, several alternate models of consent have been proposed in the literature (1) broad and blanket consent; (2) tiered consenting with options that open up possibilities of sharing for secondary use; (3) presumed sharing consent; (4) re-contacting or re-consenting for sharing purposes; (5) waived consent and (6) no consenting because only un-identifiable data was used and dynamic consent (Tasse et al. 2010; Tindana et al 2020; Munung, et al. 2015).

Beyond identifying the appropriate consent models that allows the future use of samples and associated data from genomic studies is the challenge with explaining concepts such as DNA, genes and genome sequencing in local languages to facilitate the key element of comprehensive information sharing during the consent process. (Tindana et al 2017; Tindana et al 2020). There is limited research explaining consent processes in resource limited settings in Africa as these regions are presented with challenges of poor education and economic challenges when it comes to transmitting benefits of research and its information. Firstly, the consenting process should be culturally appropriate given that this research is done in dynamic cultures. The consent should bridge the gap of understanding between participant and researchers to allow for informed consenting. In the H3Africa project descriptions such as DNA and phenotype were not described scientifically. Words such as heredity, health and disease causation were used to convey genetic information to people with limited understanding of genomics.

2.4.2. Sample and Data Sharing in genomic research

Another key ethical issue in genomics research is sharing data and samples with the scientific community beyond the primary research. Most genomic data from published research tends to be cited more in genomic research that emanates from biorepositories and consistent genomic identifiers coming from a research population (Byrd & Greene, 2020). This foreshadows the ethical hurdles likely to be encountered especially in systems where data sharing has not been explicitly spelt out. The gap between acquiring sharable data and ensuring the sharing of data shows a declining vitality despite the strides of genomic research being made in the African region. The sharing of genomic data is presented with hurdles especially where academicians are involved. The data withholding and changes in attitude were non-progressive to research in the start of the 20th Century (Campbell, 2002). The data gatekeeping was realized from the percentages of requests of data that were denied, percentages of respondents not allowed having their information released from research, the influences of withholding data and the changes of perceived willingness to share data by investigators.

2.4.2. Community Engagement strategies for genomic research in Africa

Community engagement (CE) is termed as a process of attaining objectives collaboratively with a group or groups of people on a shared goal or common interest (Tindana et. al 2014). Community Engagement is proving to be an integral part of genomic research and biobanking in Africa. Sustaining genomic research requires the creation of relationships having mutual trust and respect with communities that are involved in research (Ramsay, 2022). At the moment H3Africa is engaged with eight collaborative health research projects that are involved in 18 individual projects within 20 sub-Saharan African countries with four pilot biorepositories research projects.

The research network demonstrates the need for Community Engagement as the projects are involved in genomic susceptibility studies to specific diseases such as trypanosomiasis, diabetes, HIV, tuberculosis, cervical cancer and cardio metabolic diseases. Several empirical studies have been conducted on the continent highlighting the value of integrating community engagement into genomics studies and the various models and strategies that can be utilized by research (Tindana et al 2017). These studies have also suggested that CE provides a bridge to enhance understanding of complex scientific terminologies and can support consenting processes prior to research. For genomic research, CE can serve as a tool for sharing knowledge and ensuring that information on human heredity and genetic interactions of environmental factors are understood. CE does not come as a one-direction communication, the researchers and bioethicists are required to come to terms with the beliefs, practices and understanding of communities when it comes to dealing with diseases. Traditional explanations and experiences are taken into account as this would inform the researchers on the background as to which the community draws their philosophy.

2.4.3. Feedback of Findings in genomics research

Another contentious ethical issue in genomics research is the question of whether and if findings should be shared with research participants and local communities (Matimba et al 2022; Tindana et al 2020; Mwaka et al 2021; Ochieng et al 2022). Results are usually presented back as individual results, aggregate results (embodying populations which have been under study) or incidental findings which were supplementary to the generated results. Individual results are person specific and entail genetic information that concerns an individual and their lineage, the individual is usually taken through genetic counseling for handling information that may be given out and to prevent distress or misrepresentation of information offered.

Aggregate results for genomic research are given to collective groups of people involved in research. The aggregate results do not offer specific information and are ideal for maintaining anonymity and secrecy for individual persons. Despite the nature of aggregate results being collective they too are prone to unethical use. The aggregate results require the information to be used with goodwill, fair practice and to ensure the benefit of the populations involved. For aggregate results feedback researchers are mainly concerned with the integrity and social benefit of research (Kisiangani et. al 2022). The interests of individuals in research are usually unheeded in genomic research. Researchers argue that the return of results to individuals can have important information which can end up being worrisome to them. In such scenarios the risks of sharing individual information end up outweighing the benefits. Genomic research results are sharable to individual participants as sharing upholds the duty of care of researchers, enhances good practice and the moral respect of participants. Researchers are best placed to device methods of sharing the individual genomic information that is generated from research. Arguably, the sharing of genomic results aggregately is considered 'sharing knowledge' rather than the 'returning of results'. Genomic research can only have enhanced impact if properly embraced by communities and if the communities understand the value of genomic research (Ravitsky et. al 2006). Community engagement is best suited in addressing the gaps of understanding of participant communities and researchers. Results communicated back to communities appropriately boost their sense of uniqueness. For research that is solution oriented the feedback of results can be tailored with counseling or data dissemination techniques. Notably, a majority of the results focusing on individual-specific genomics is usually brought out by capital intensive research bodies of private-funded equity (Brinegar et. al 2017). Apart from results feedback being considered by researchers, the research network can be able to go an extra mile depending on their motives and their fiduciary responsibility in the research industry. For companies that can

extend their efforts of data utility beyond the scope of research work to health service management, the participants can be brought onboard to vouch for development of useful data in clinical precision and to allow for them to benefit. Improvements in handling biodata and biological samples are embedded in data-sharing practices and policies that are beneficial, by extension, to the general public (De Vries et al., 2014). Some key research institutions link the general public with research data from communities that are involved with precision medicine for rare illnesses thus improving reciprocity (Campbell, De Vries et al. 2015)

Genomic studies have raised interest among researchers in mapping and determining the prevalence of physiological diseases. Bubela (2006), noted that human genetics can indicate the causal mechanism of diseases that indicate resistance or susceptibility. Such data is crucial in healthcare and affiliate institutions in providing long-term solutions to affected communities. However, questions remain on how results from genomic studies should be effectively communicated with individual participants and this has led to a growing number of empirical studies currently ongoing across Africa to identify best practices to inform guidelines, policies and practices.

2.5 Privacy and Confidentiality

Wan et al. (2022) notes that genomic data privacy concerns the public, particularly when they realize their genomic information has been shared with third parties. In recent years, genomics has witnessed a surge in demand due to its usefulness in pinpointing disease-associated genes. Privacy policies in genomic data are being developed to address these concerns as researchers are interested in acquiring knowledge while using viable genomic databases. The protection of genomic databases implies that researchers should be sensitive to how such information is used,

modified, or distributed. In an article by Holden (2009), the risk of data being used before embargo periods is a potential risk to ethical genomic data management. In a research data misgovernance ordeal, genomic datasets from an African native population got shared with commercial entities without clear guidelines between partners involved with the research; this strained the relationships of collaborative partners involved with the project (Stoksad, 2019). The literature suggests that research stakeholders need to formulate a comprehensive database protection policy that safeguards the interests of researchers managing data and the participant sharing genomic information during research processes (Campbell et al., 2015). Such moves will ensure that research becomes a collaborative effort, as opposed to a monolithic endeavor. Participants should be assured that their information is respected and that privacy protection measures are implemented. The measures ensure that all exchanges of genomic data are conducted within stipulated legal boundaries, which indirectly entails establishing informed consent procedures and policies concerning management, access, and exchange of personal genomics that ensures confidence in genomic research contribution (Wan et al., 2022).

Alarcón Garavito et al. (2023) have noted that genomic screening had been used in various procedures, including prenatal diagnosis of maternal diseases, early cancer detection, and congenital disabilities. Such methods have proven to be practically successful in clinical cases. However, such procedures have limitations as they require highly experienced professionals to interpret the screening outcomes and assist individuals requesting genetic testing. Genomic researchers involved with the H3Africa Research consortium advocate for a robust research process to ensure quality information in research. Researchers argue that policymakers should consider introducing laws that protect the rights of individuals with certain genetic traits who consent to participate in genomic research. The current genomic data sharing policies are limited

to protecting individual data privacy and ensuring that individuals are not harmed by advances in genomics research techniques, resulting in compensation for damages incurred to health or property.

According to research, commercial entities have policies that promote data sharing motivated by financing structures (Capalbo et. al 2020). Corporations use personal genomics data to identify genetic anomalies and correlate them with health risks such as carrier genes for phenotypical diseases and infertility. The genomic data has proved to have distinct use in pharmacokinetics and preventive health measures; therefore, such data is needed in development of health care service products and management of patients. Sharing participant genomic data for commensurate gain can be considered unethical because information is considered private if informed consent allowing sharing from the onset of research is not given (Capalbo et al., 2020). The same concern is raised by research teams that develop algorithms expounding on inaccessible data from the field of genetic research. Investigative algorithms can indicate exposure to diseases even without having a disease yet, especially when assessing participants having carrier genes for phenotypical diseases. The current research design for studies needs regulations to protect individuals from non-consented data sharing. Commercial entities using personal genomics data should receive education from bioethics researchers on its ethical and moral implications on participants, as they are sometimes unaware of possible privacy rights infringements. Information shared should be used only for its intended purpose, and its purpose should be explicit to ensure it is not being abused, in perpetuating social stigma, inciting racism or conforming to health insurance bias.

2.6 Data Sharing Policies in Research

Data-sharing practices have existed for nearly two decades in developed countries (Kaye et al. 2009). The effect of these practices is not to be neglected as they impact broadly on how information is spread. The harmonization of genomic data-sharing practices is essential in stimulating data-intensive research. Research infrastructures in bio-banking resources and the International Public Population Project in Genomics (P3G) are international bodies that offer digital methods to govern genomic data (Knoppers et al., 2014). P3G stipulates a method for the generic sharing of genomic information through privacy, liability, security, and delivery-based methods. The Global Alliance for Genomics and Health has created a responsible Genomic and Health related Data Framework to support the international agenda (Shabani & Knoppers, 2015). Despite the harmonized international agenda, there are inconsistencies in different jurisdictions and cultural beliefs of different backgrounds. Advocating for genomic de-identifiers comes across as ineffective since Deoxyribonucleic acid (DNA) is a unique individual attribute for individuals (Shabani et al., 2014).

Currently, researchers are tasked with meeting the demands of funding agencies, fulfilling the expectations of participants, and getting ahead in their careers, which tends to present a compounding burden. Funders are challenged with ensuring the trust given to them by the public does not deteriorate and that the funded research generates valuable knowledge that is spread and developed. Data-sharing frameworks of research governing bodies balance the sustainability of relationships between funders, researchers, and the public. Public goodwill and trust would require sound and ethical research, even in community engagement with healthcare sector players (Kaye et al., 2009). The challenges in data sharing can be met explicitly with research and contemplation of the perspectives of concerned parties (Kaye et al., 2009). A policy that

could be implemented to improve the goodwill of data sharing to communities by commercial entities would include a code of conduct to ensure that personal genomics data is used only for its intended purpose. The demand for personal genomic data suggests that there is a need for regulations protecting individuals from non-consented data sharing and obtaining medical information without consent.

2.7 Genomics Knowledge translation and Role of Commercial Entities

Translational genomics can potentially improve patient care in genomics and this has already been taken up in developed countries. In developing countries, however, the translation of genomics to clinical benefits has been stagnated by divergent national policies that are incoherent, a lack of adequate genomic scientists, and poor research infrastructure (Tekola-Ayele & Rotimi, 2014). Despite the challenges existing in these low-income countries, initiatives such as H3Africa, the Qatar Genome Project (QGP), and the Mexico National Institute of Genomic Medicine (INMEGEN) have stepped in to address the challenges presented in research (Tekola-Ayele & Rotimi, 2014). These intervention programmes have identified the need to contribute to resource distribution, sociocultural equity, and equitable policy formulation.

Advancements in the clustered, regularly interspaced short palindromic repeats (CRISPR) have shown promise in the development of mass-scale manufacturing of cost-effective products applicable in human therapeutics and translational medicine. In a survey by Brinegar et al., 2017 the application for CRISPR technology in the United States from 2013 to 2017 showed to have many industrial and equity-funded players; the majority of players in a total of 45 investors being capital firms (Brinegar et al. 2017). Thirty commercial companies of the 45 focused on gene editing, while twenty-five of these firms were healthcare or biotechnology focused. The disease burden in Africa stands to benefit from gene editing technology such as these, especially

in treating communicable diseases such as HIV, Malaria, and Tuberculosis (Mudziwapasi et al., 2018). In this case, the private healthcare sector can effectively meet the knowledge and resource gap, albeit with some ethical concerns. The African socio-economic gap in genomic research advancement and beneficence could aim for supplementation from the private sector in a manner spurring economic growth without monopolistic practices of highly funded organizations that may convey lack of transparency and red-tape bureaucracy in data use.

In the United States there is already direct-to-consumer (DTC) genomics through capital-intensive practices that are seeing some commercial genomic research institutions thrive. DTC genomics has been described as a divisional scene in developing genomic research and benefits (Allison, 2012). The scope of benefit and target objectives for such research purposes can be dynamic and variable across a population. Organizations that have the information and resources can choose to contribute to the debate for translational genomics. Messages about the benefits of translational genomics need to be compelling to grasp public interests effectively if taken up by organizations. Because genomic programs are expensive and sophisticated, advocacy campaigns must bring out the benefits of genomics in other disciplines e.g. Community heritage and descendant history, aside from medicine to echo the benefits of sustaining such research in African communities.

Despite the scientific arguments supporting the sharing of genomics data with commercial companies, the subject evokes a lot of controversies given that the term commercialization itself often suggests a profit-making venture or 'selling' of human biological samples and associated data at the expense of research participants. In the implementation of the H3Africa projects, anecdotal reports from the field and participating communities suggested that data sharing with commercial companies may not be ethically acceptable unless there is a clear plan for benefit-sharing arrangements. Also, local terminologies used in explaining the term commercialisation

may be problematic. Thus, a commissioned H3Africa Report on Informed Consent and Commercialisation (H3Africa 2021) recommended the need for a uniform terminology for concepts such as selling and profiting in relation to commercialisation. Secondly, consent forms should be explicit that researchers are not selling human samples for profit. Thirdly, researchers should avoid using the term 'commercialisation' vaguely in consent forms and during communications with communities and study participants as the context may be misconstrued.

The report also recommended that community engagement processes for studies involving the sharing of biospecimens and/or data, should include a discussion about commercialisation and called for "more empirical research" to explore the perspectives of key stakeholders. This present study aims to contribute to the existing literature by addressing the latter recommendation. It explores the perspectives of research participants, research staff and other key stakeholders on the ethical aspects of data sharing with commercial entities (H3Africa 2021).

2.8 Theoretical framework: Reciprocity in Genomic Research

Beauchamp and Childress (2019) focused on the biomedical ethics principles of respect for autonomy, beneficence, justice and non-maleficence. These principles were observed to be foundational in research ethics and healthcare provision. The expectations of patients and research participants are usually accommodated within these principles. Upholding these principles builds on the trust and cohesion of research stakeholders. The relationship between research stakeholders is usually founded on principles that foster justice and beneficence, autonomy and non-maleficence.

Globally research and healthcare are usually comprised of the principles of ethics paradigm mentioned above. Even though the ethical implications are definite the application of these ethics are usually applied exclusively in various societies. The African ethics and ethicists are usually focused on communal benefits of research and healthcare (Tangwa, 2023). Despite genomic research having a potential for communal benefits, the interactions to achieve these have not been fully explored. Adeate (2023) as an ethicist argues for the shift from individualistic focus of research to communal benefits to leap the gaps that are experienced in healthcare. Practices such as those of the Ubuntu-model in South Africa show the benefits and cohesion achieved from research bio-repositories that are managed communally (Moodley et .al. 2019). Whether these models can be replicated across the region of Africa remain arguable. The interaction of genomic research data and research stakeholders could place the data in institutions of commercial interests.

The policies for genomic data sharing encompass the sharing of data with institutions seeking to translate the data for health benefits in the public or private healthcare sector thus benefitting the communities from which genomic data mining is done. Despite extensive research, the materials and genomic data obtained from research in Africa are not utilized fully in knowledge and healthcare development due to lack of political support, skilled labor, funding and overstretched healthcare systems (Kamp et al., 2021). Understanding the ethical issues and problematic policies in genomic data sharing with commercial entities can streamline future relations of genomic data users, contributors, and researchers allied to different funded groups. A better understanding of ethical data-sharing practices would do away with data-sharing policies that do not foster beneficial community research while maintaining the ones that do. The beliefs and cultures of African communities in commerce interactions of research and the health industry can demonstrate their expectations, their understanding of data-sharing practices, and the

reasons they would need data to be shared or restricted from commercial enterprises in the first place. This study draws on the theory of reciprocity by Serge-Christophe Kolm which provides valuable framework for understanding social interactions, exchanges, and relationships (Kolm, S.C 2000). Reciprocity is defined as 'the conduct that can provide fairness in freedom, sustainable altruism and mutual appreciation of certain intensities' (Kolm S.C 2000). Other authors, such as Molm N, define reciprocity as 'the giving of benefits to another in return for benefits received (Molm N 2010). One basic idea that underpins social interactions is reciprocity. Individuals are driven to return favors or acts received from others, which creates a dynamic interplay of giving and receiving. In the context of genomics research, data sharing would mean individuals giving their genomic data to institutions and commercial entities to advance scientific research and in return receive something back. The question is what should commercial entities give back to individuals and communities for accessing their genomic data?

According to Kolm, there are different types of reciprocity: generalized reciprocity (acts of giving without expecting anything in return), indirect reciprocity (acts of giving that is influenced by reputation and social norms), direct reciprocity (one-to-one exchanges). He also suggests that different forms of reciprocity: Economic Reciprocity: In economic transactions, reciprocity manifests through exchanges of goods, services, or monetary payments. However, Kolm emphasizes that economic reciprocity is not solely driven by self-interest but also by social norms of fairness and equity (Kolm S.C 2000).

Beyond economic exchanges, reciprocity also operates in social interactions, where individuals reciprocate gestures, favors, or emotional support. Social reciprocity contributes to the formation of social bonds and networks, fostering cooperation and cohesion within communities. Kolm also introduces the concept of moral reciprocity, which emphasizes the

ethical dimension of reciprocity. Moral reciprocity entails treating others with fairness, dignity, and respect, regardless of immediate self-interest. It underpins notions of justice, equality, and human rights.

Reciprocity is shaped by social norms, cultural values, and institutional arrangements that define acceptable behavior and expectations in interactions. Norms of reciprocity vary across societies and can influence the extent and nature of reciprocal exchanges. Trust also plays a crucial role in reciprocity, as individuals are more likely to reciprocate when they trust others to uphold their end of the exchange. Reputation serves as a mechanism for enforcing reciprocity, as individuals may alter their behavior based on others' reputations for reciprocity or fairness.

Reciprocity may also be influenced by power dynamics within social relationships or institutional contexts. Unequal power relations can affect individuals' ability to reciprocate or negotiate fair exchanges, leading to asymmetrical patterns of reciprocity.

Kolm's theory has implications for theories of distributive justice, advocating for redistributive policies that address inequalities and promote fair exchanges. Redistributive justice seeks to ensure that resources are distributed in a manner that respects principles of reciprocity and fairness.

Policies promoting social welfare, such as social insurance programmes or public goods provision, can be seen as manifestations of generalized reciprocity, where individuals contribute to collective benefits with the expectation that others will reciprocate when needed. Solidarity-based approaches emphasize mutual aid and support within communities, fostering social cohesion and resilience.

Critics may argue that Kolm's theory of reciprocity overlooks cultural variability in norms and practices surrounding reciprocity, which can shape the nature and extent of reciprocal exchanges. There may be debates about the relative importance of individual motivations versus structural factors in shaping reciprocity. While Kolm highlights individual preferences for reciprocity, structural constraints and power dynamics can limit individuals' ability to engage in reciprocal exchanges. It highlights the multifaceted nature of reciprocity and its implications for understanding and addressing social inequalities and promoting cooperation within societies.

2.9 Summary of Gaps in Knowledge

Data sharing in Africa is limited by low expertise, bureaucracy and limited education levels. The elimination of data sharing hurdles proves to be complex in the African research environment due to different indigenous cultural environments and oversight communities. Despite thesechallenges participants in the region require genomic research data to be cross-fitted to their healthcare management and this would likely happen with genomic data sharing with commercial industry players who are highly impactful.

Elimination of boundaries in data sharing is faced with complexity, while nuances of socio-economic impact in the potential of genomic data utility are not fully experienced within Africa. Studying and sharing stakeholders' perspectives around ethical principles in data sharing with commercial entities would unlock impactful transferrable benefits for participants and researchers alike, especially in translational genomics, preventive care of non-communicable diseases and management of rare genetical diseases.

CHAPTER THREE

3.0 METHODS

3.1 Introduction

This chapter describes the methodological choices made in the research design and approach. It describes the study design, the data collection methods and analysis as well as the ethical considerations that guided the implementation of the research.

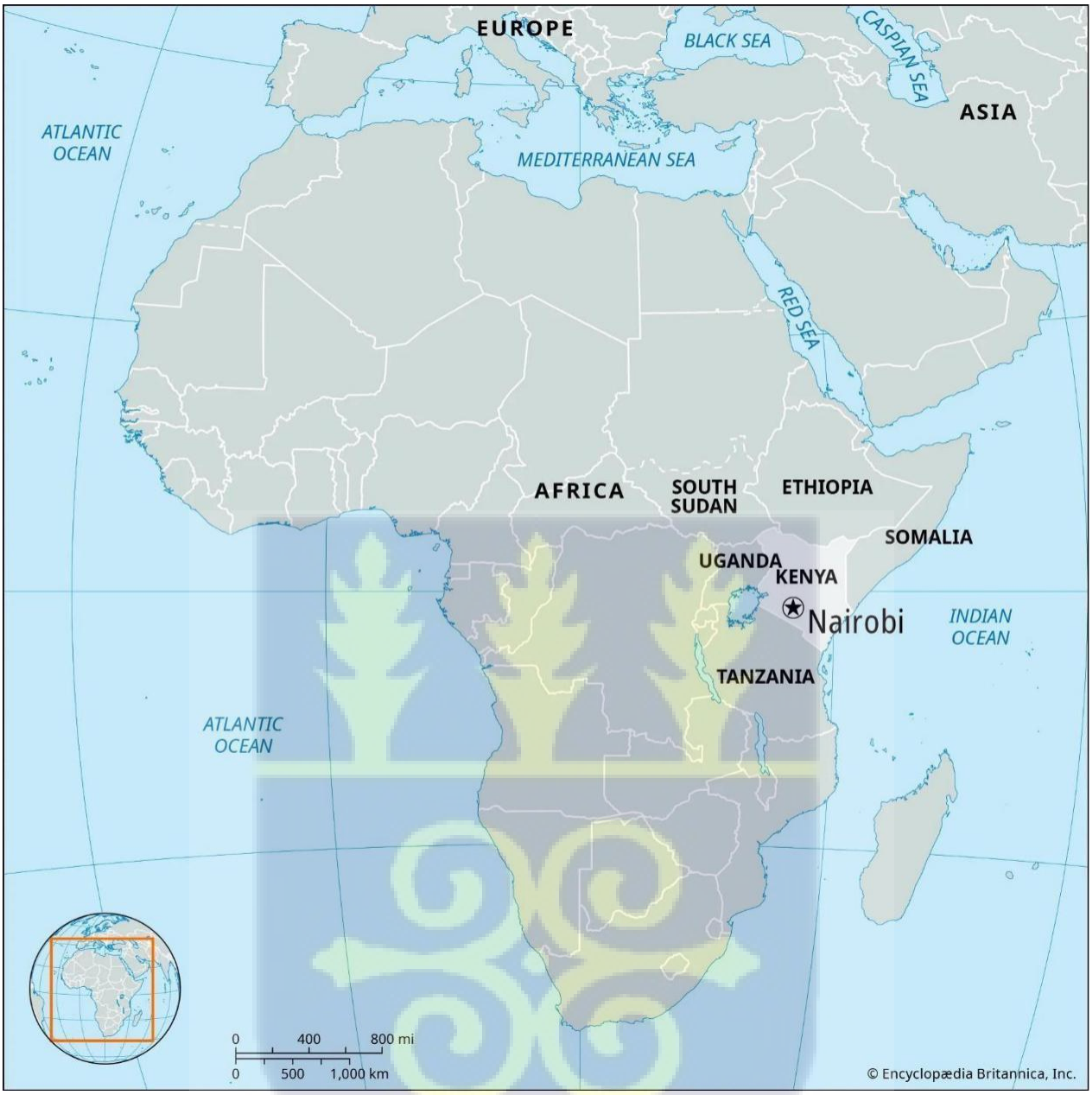
3.2. Research Design

The study employed an exploratory qualitative research approach involving observation and semi-structured interviews. An exploratory qualitative study design is an approach employed to gain a deeper understanding of a phenomenon or explore a new area of inquiry where little prior knowledge exists – ethical aspects of data sharing with commercial companies (Corbin and Strauss, 2007; Cresswell 2014). This type of study is characterized by its open-ended nature, flexibility, and the absence of preconceived hypotheses. The research design allowed the analysis of data-sharing practices in depth within the context of the H3Africa CE-BioGen Project in Kenya.

3.3. Study Area

The study was conducted in three geographical locations within Nairobi, Kenya's capital city.

Figure 3: A Map showing the location of Kenya's capital city



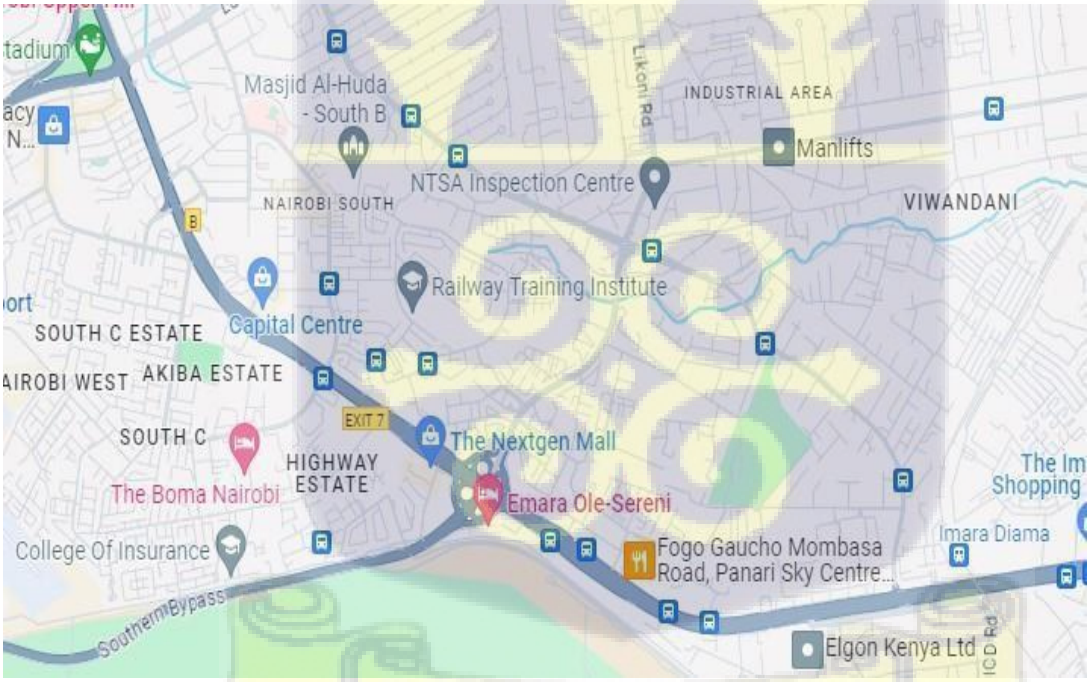
Source: Google Images

(1) Viwandani

Viwandani is an informal settlement in the County of Nairobi (Makadara Constituency) situated

10km from Nairobi Central District. It is bordered by Nairobi's Industrial Area which is a hub for manufacturing and processing industries. The settlement area is characterized by semi-skilled workers and an income generating work force. The population dependent on formal employment are usually prone to migration relative with the availability of employment. The AWi-Gen Project collaborated with APHRC to achieve their research objectives in the areas of Viwandani and Korogocho. The AWI-Gen Project targeted participants aged 45-65 for their cohort studies in these areas. APHRC having been involved in both the Health Demographic Surveillance Systems and previous research projects with the communities ensured efficient running of research operations.

Figure 4: A map showing the location of Viwandani informal settlement in relation to Nairobi Central Business District.

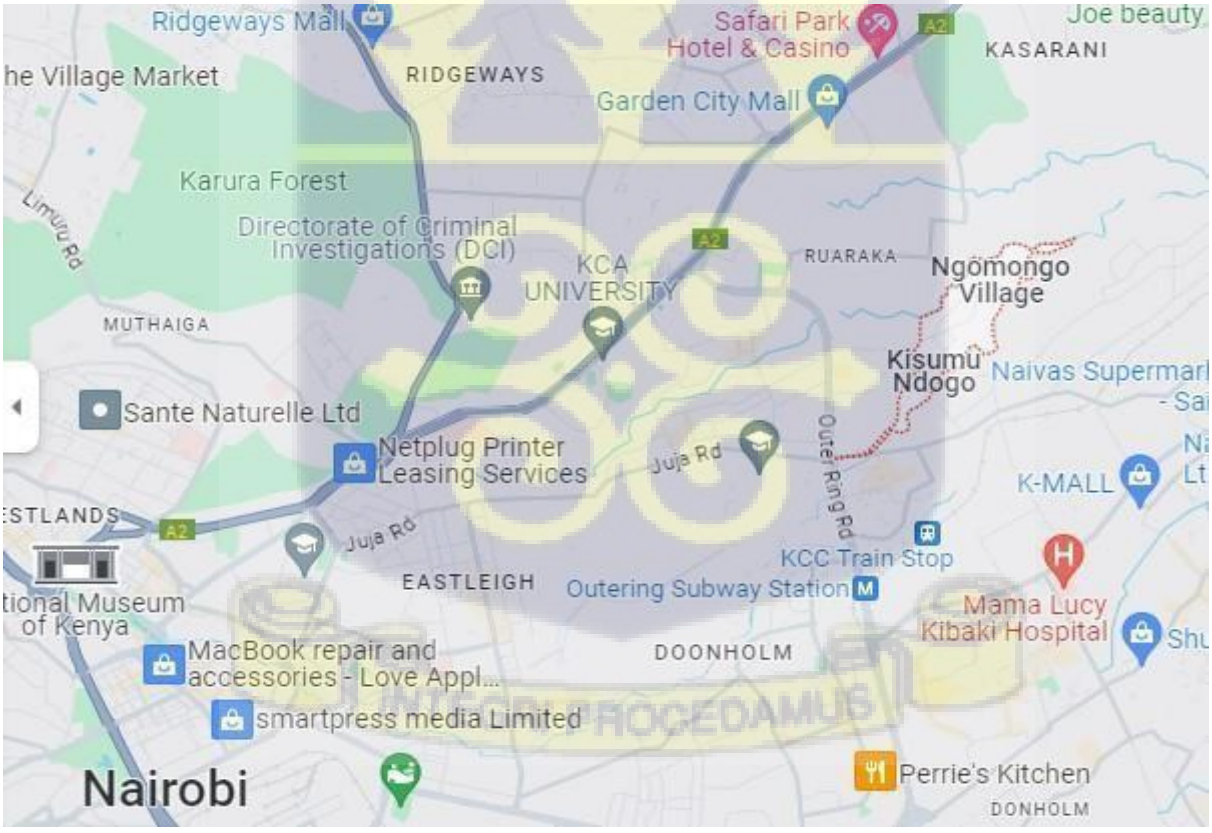


Source: Google Maps Images

(2) Korogocho

Korogocho is a semi-informal settlement in the County of Nairobi (Ruaraka Constituency) nearly 15km from Nairobi's Central District. The area comprises of Kisumu Ndogo, Highridge, Ngomongo and Grogon demarcated as separate villages. The indigenous communities there were settled in the early 1980's as squatters from land reparations by the government. The long-term resident communities comprise of Kikuyu and Luo tribes. The communities are more dependent on informal employment and most of the aged population have low education levels than the young people of that community. The AWI-Gen Project targeted participants aged 45-65 for their cohort studies in these areas. APHRC collaborated with AWI-Gen to ensure research objectives of community engagement and demographic surveillance were met efficiently.

Figure 5: A map showing the regions Kisumu Ndogo and Ngomongo within Korogocho informal settlement in Nairobi



Source: Google Maps Images

(3) African Population Health and Research Centre (Nairobi Campus)

The African Population and Health Research Centre (APHRC) is a premier research and policy organization in Africa. It has contributed to population research and health research to foster the well-being of African people. The institution has a West Africa Regional Office (WARO) situated in Dakar, Senegal. The Centre has research leaders shaping policy making and drive for change in research data utility across sub-Saharan Africa. The Centre's portfolio includes over 100 projects in more than 35 countries. The Centre now partners with other Research institutions and even Government to inform policy making with over 20 years in research. In Nairobi, the research campus is located in Kitusuru, nearly 20km from Nairobi's Central Business District.

3.3. Study Population

The research focused on assessing the views and perceptions of participants involved in the AWI-Gen/ CE-BioGen project on data sharing in Kenya. The target population therefore genomic study participants, researchers, and community health volunteers. The participants were researchers from APHRC offices in Kitusuru and research participants from Viwandani, and Korogocho in different communities within Nairobi. The study participants were recruited based on the following considerations: -

- *Timeliness and data availability:* The researcher determined the timeliness of usable information and participant availability to ensure data access. Following their experience with the research study and continuity with the AWI-Gen Project, participants were sought

after. The participants who were inaccessible were mobilized for phone interviews, while the ones within the locality were interviewed face to face.

- *Location and context:* The research was conducted according to the locality of the participants. Participants were from two locations, Korogocho and Viwandani, within Nairobi, Kenya. The two locations were socio-economically different; one community had domiciled community members while others had industrial contributive members. The responses were collected from the respective communities and with the level of understanding and exposure prevalent within the community. The case study of the AWI-Gen project gained information accumulatively in two phases spaced by five years. The research method allowed for introspection of experiences, preferences, and inclinations of genomic data sharing with commercial entities. The researcher sought to identify how the individual and experiences could be described and analyzed to address research questions.
- *Selection based on recommendation:* The researcher sought the involvement of select players with experience in general genomic data sharing and data sharing practices. The selection also involved people recommended from their ethical research practices in Ethical and Scientific Review Committees. Before the interviews, the stakeholders were taken through their previous research engagement with AWI-Gen to prepare them for qualitative data collection. Given the time after the last engagement, the recap was necessary to bring members up to speed.

3.4. Inclusion and Exclusion Criteria

3.4.1. Inclusion criteria

The study purposively selected the following key stakeholders who were involved in genomics research as implementers, reviewers, data managers and research participants:

1. *Genomic researchers:* These are skilled researchers involved in the capacity of health and clinical diagnosis from the prior phases carried out within the AWIGEN team.
2. *Ethics Review Committee Members:* The members of review committees who participated in the review and approval of genomics studies in Kemya were sourced according to their experience and wealth of knowledge regarding genomic data sharing.
3. *Data managers* are skilled workers tasked with the management and analysis of genomics data.
4. *Community engagement personnel*: These are skilled or non-skilled workers used in the mobilization and the involvement of targeted participants before and after their scheduled project site visits in the field.
5. *AWI-Gen research participants*: AWI-Gen research participants are a cohort of selected individuals who were engaged personally for reasons of sample and information retrieval.

3.4.2. Exclusion criteria

Participants who met the inclusion criteria but refused to grant informed consent or were unavailable at the time of data collection were excluded from the study.

3.5. Sampling technique

The study employed a purposive sampling technique, given the participants' experiences in the AWI-Gen Research Project. The Nairobi participants were selected by the researcher due to his close proximity and prior community engagements in research. This allowed for the researcher to be able to navigate the terrain and relate with ethical narratives of the region.

The sampling was piloted by researchers who had been involved with Genomic Research within

AWI-Gen, some of the participants were exposed to mock interviews during the piloting process and the model questions were run through for validity and objectivity.

The study employed a purposive sampling technique, given the participants' experiences in the AWI-Gen Research Project. The participants were grouped in terms of their prior experience with APHRC, subject topic understanding and the level of previous engagement employed, i.e., community members involved in extensive mobilization and training engagement efforts, were prioritized. For research staff participants, the sampling was done according to the level of

engagement they were involved in the AWI-Gen project and their research ethics experience.

3.6. Data Collection Tools

The researcher developed a data collection In-depth interview (IDI) guide and an FGD guide (Appendix A) for each category of respondents that was targeted for interviews to address the set objectives of the study. The guides for IDI and FGD were structured into four parts which were:

1. Interviewee background
2. Experiences with genomic research projects
3. Participants understanding of data sharing policies and trends
4. Perceptions of genomic data sharing with commercial entities.

3.7. Data Collection Procedures

The data was collected through interviews and focused group discussions (FGDs). The interviews were conducted face to face. The participants were sought and scheduled for interviews in offices discreetly and promoting of free speech. The participants were taken

through an informed consent to acquaint them with the procedure of the research. Any queries to the research process were handled acutely before the research. Research participants were asked to pick between Swahili and English that would be used in the interview process

The consent forms explicitly mentioned the recording of audio to promote ethical data retrieval. Data were collected using an In-Depth Interview (IDI) Guide (Appendix 2). Qualitative data were generated to respond to the data objectives. 27 interviews were done in total and 6 focused group discussion (FGDs). From the total interviews 7 interviewees were professional researchers while 25 were research participants.

3.8 Data Management and Analysis

The interviews were conducted either in English or Swahili according to appropriateness and comprehension. The audio recordings were then transcribed verbatim to English. The meanings of words of local dialect were transcribed with their meanings maintained.

The study employed thematic analysis as the data analysis method. Narrative and thematic analysis were applied to qualitative studies as they produce intensive and rich descriptions (Yin, 2009). The researcher analyzed the data generated using Dedoose Version *9.0.17*, cloud application (Dedoose, 2021).

The analysis of qualitative data was both thematic and narrative. In each case the following reasonings were used.

(1) Thematic analysis

The data was assessed using Dedoose Version 9.0.17 to reveal information embedded in raw data. The use of *a priori* codes was done to retrieve information through deductive reasoning. Themes of autonomy, beneficence and informed consenting were explored deductively in genomic data sharing.

(2) Narrative analysis

The data was analyzed to interpret research participant perspectives on various subjects. The use of inductive reasoning was used to allow for contexts to form narratives without prior coding. The narratives were used to induce perspectives of beneficence, non-malfeasance and fidelity in ethical data sharing. The imploring of previous experiences of genomic research was an example of induction to create narrative analysis.

The analysis tool was used to decode themes, relate excerpts and make highlighted memos from transcripts applicable to inducing new narratives and perceptions. The contributing insights from existing or new concepts explained social behavior and thinking (Yin, 2013). The analysis also intended to acknowledge the potential relevance of multiple sources and avoid single sources of evidence and interpretation for the research topic.

3.9 Reliability and Validity

The reliability of a qualitative study, as described by Mugenda & Mugenda (2003), is said to be the accuracy and the precision of a measurement procedure, together with a valid degree of relevance of the data representation to the phenomena being studied, allows for the use of data. Throughout the data collection process, the researcher maintained the trustworthiness of the data collected by being aware of the factors influencing or affecting the views offered by participants. Community engagement procedures were used to prevent the withholding of contribution of the participants, especially those likely to encounter recall bias. Suitable data for analysis was isolated and studied using purposive judgment and employing the predictions of credibility for the involved participants. Constructive codes and themes were weaved from the total interviews done. Regarding reporting, the results were assessed clearly from audio to put out transcripts that could be analyzed with Dedoose *9.0.17 (Dedoose, 2021).*

3.10 Ethical Consideration

3.10.1. Ethical Clearance

The research proposal was submitted to the Ethics of Scientific Review Committee (ESRC) of the African Medical and Research Foundation (AMREF) Kenya for ethical clearance before data collection commenced.

The research was proposed in a setting of researchers in APHRC and supervisors within the fraternity of the University of Ghana. Similarly, the research was reviewed by an independent Review Committee comprising of a panel of independent reviewers from the African Medical and Research Foundation under the following code P1367-2023 and the tracking ID was active throughout the collection of data and the development of the research.

3.10.2. Informed Consent

The process of obtaining informed permission was conducted via face-to-face interviews. The participants were informed about their involvement in the second phase of the AWI-Gen trial over the period spanning from August 2019 to December 2020. The research objectives of AWI-Gen were revisited by the participants, who were thereafter provided with thorough descriptions of the consent process. Participants maintained a copy of the informed consent form, while the researcher maintained a separate copy. The participants also consented to the recording of individual and group audio interviews that were held.

3.10.3. Risks and Benefits of the Study

The study risked divulging information that would have been protected in data use agreements affiliated with the case study project of AWI-Gen. There was also a risk of attaining information

from presently biased members of the AWI-Gen project. The benefit of this study includes the integration of genomic data sharing ethics to bring out cooperation of research-oriented users of genomic data both in the research field and the commercial healthcare sector. The benefit of the research involved transferrable benefit-sharing between participants and researchers.

3.10.4. Privacy and Confidentiality

The participants' identities were protected during the data gathering process, and the opinions expressed did not disclose any personal information. The acquisition of data was facilitated by the involvement of community health professionals who were widely recognized within the communities under investigation. The participant information was withheld from research personnel who were not involved in this study, and data management protocols were used to ensure that unnecessary sharing of information did not occur.

3.10.5. Voluntary Participation

Participants were assured that their participation was completely voluntary and they could refuse to participate in the interviews without any penalties. They were also assured that they had the right to withdraw from the study at any stage.

3.10.6 Conflict of Interest:

The researcher declares no personal or professional interests that could potentially influence the integrity of the research and its objectivity.

3.10.7. Data Privacy, Security, Storage, and Usage:

Participants were identified by code numbers, ensuring their anonymity throughout the research process. Hardcopy data were stored securely, and electronic data were password-protected and stored on a secure

server. Only authorized individuals had access to the research data. After two years, all data would be securely destroyed in accordance with ethical guidelines.

3.11. Funding

This study was supported by the H3Africa Community Engagement in Biobanking and Genomics project (CEBio-Gen) with funding from the United States National Institutes of Health (NIH) and the National Human Genome Research Institute (NHGRI).

CHAPTER FOUR

4.0 RESULTS

4.0 Introduction

This chapter presents the key findings of the study. It begins with the background information of the study respondents, followed by a presentation of the results under each of the specific study objectives.

4.1. Background Characteristics of study respondents

The individuals involved in the AWI-Gen study project were between the ages of 40 and 65, whereas the researchers themselves were under the age of 50. The educational attainment of previous project participants was predominantly below the tertiary level, whereas the majority of researchers possessed graduate-level or post-graduate level education.

Table 1: Background characteristics of study participants

Target Group	**Type of interview conducted**	**Number of interviews conducted**
Genomic researchers	In-depth interviews	2
Data Managers	In-depth interviews	4
Members of Research Ethics Committees	In-depth interviews	1
AWI-Gen Study Participants	In-depth interviews Focus group discussions	19 6
Community member	In-depth interviews	1
Total Number		33

CHARACTERISTICS	Number of Participants
Gender	
Male	15
Female	18
Age (Years)	
20-30	1
30-40	5
40-50	4
50-60	14
60-70	9
Educational Level	
Masters	2
Graduate	3
Diploma	2
Below O-Level (KCSE)	28
Institute	
APHRC	7
Unaffiliated persons	26
Work position	
Senior Researcher	1
Research Fellow	0
Researcher	6
IRB member	1
Community Health Workers	4
Informal employment	21
Residence	
Viwandani	13
Korogocho	13
Nairobi (unspecified locations)	7
Duration of experience with banked samples	
>10 years	1
<5years	3

Table 2: Respondents' Characteristics

4.2. Perspectives on the ethical aspects of data-sharing

Objective one of this study was to explore the perspectives of researchers, research staff and research participants on the ethical aspects of data sharing with commercial. Three key themes emerged from the data: the scientific and social value of genomics data, appropriate consent

models to support data-sharing with commercial entities

4.2.1. The scientific and social value of genomics data

The Human, Heredity, and Health in Africa Consortium has conducted extensive research, resulting in the collection of genomic data from a substantial cohort of more than 70,000 people (Ramsay, 2022). The participants in this study were of the view that data generated from genomics research hold potential value for utilization within the health sector of the African area.

One of the researchers expressed the viewpoint that the AWI-Gen data had the potential to yield exponential discoveries. She articulated as follows:

> "*A lot could be done from the samples and the measurements we took in the field, and I believe there would be more extensive use of such data and other innovations in research; therefore, there would be a need for sharing the data.*" **(Interviewee 7, FW)**

Despite the potential use of genomic data, one of the interviewees, an expert researcher, expressed the need for an increase in the number of geneticists for genomic data to be usable. The interviewee noted that the research projects are specific and that any alternative use would require the expertise of geneticists. The current African situation shows there is low uptake of genomic research, and the research team cannot go beyond the targeted objectives mainly due to limited skilled labor and capital resources. The need to boost genomic data utility would also include an element of fidelity to health service projections and beneficence to the end users. Data could be used to gain unfair market advantage in pharmacogenomics or even to furnish parallel market economies such as insurances and drug marketing.

The lack of human resource in Africa to work on genomic studies also affected the stakeholder's view on the ethics of data sharing. Sufficient geneticists in Africa are lacking and this has made data sharing between researchers and the private sector players in overseas Research institutions in healthcare essential. Genomic data seems to flow where the utility of human resources and capital in genomic research is high. The ethics of genomic data sharing is inextricably linked to the resources facilitating the utility of this data, and this would involve the capital assets of analyzing samples and conducting genetic research. A researcher working with data manipulation had the following to say;

The exploitation of genomic data after collection has not been finding channels to be of more use despite its myriad types of information **(Interviewee 1, Researcher).**

A researcher with policy engagement and ethics background, sensitized on the time consciousness of assessing research data use after obtaining feedback. Shipping of samples abroad was also cited as a concern to a small number of participants, and addressing such concerns through more elaboration of the researcher's intent would aid in compliance with bio-data proliferation even to other research entities and even commercial entities. She was quoted saying...

> *"The lapses of a long time in relaying of results by the research team is met with uncooperativeness, especially during mobilization and engagement of research objectives for cohort studies."* **(Interviewee 10, Researcher)**

Deliberative forms of consultation or influences of those concerned were avoided. The negative

and positive possibilities of genomic data sharing were discussed with the participants. The research employed diagrams and language diversity to express the idea of genomic data to participants not yet acquainted with the subject. The effectiveness of demonstrations showed a necessity for informative engagement if genomic data sharing is to be explored, especially in the targeted communities; the recall bias and low exposure to genomic understanding required symbolic references in language and description to bring the concepts to their fingertips. One aspect affecting the ethics of genomic data sharing is the distinction and value placed on using genomic data within the research by participants. Data distinction could be termed as placing of a value base for the essence of genomic data by the participants. For participants of this research, demonstrating the need for genomic data sharing was directly proportional to the value and distinction of genomic data value across all collectible data gained from the field. Data deemed valuable by community member standards was highly likely to be favored for sharing by community stakeholders. This was so, due to the optimism of health service benefits accruable from data distribution.

The AWI-Gen study communicated rapid point-of-care screening tests during recruitment, which participants highly appreciated. 47% of the interviewed participants could distinguish the different forms of data collected in the field; this acutely affected the perceptions they could form on genomic data sharing value. The latent value of genomic data in research requires stakeholders to understand a portion of genomic study objectives in present and future research. The bio-data collected from routine screening was more relatable to participants than the genomic data. Similarly, participants associated highly with their samples while being under-equipped with the knowledge of genomics studies and the potential for future use of samples. Notably, participants based more value for research material

collected from them than the genetic information obtained from such data leading to a mismatch of moral values especially when the information or data collected from research material is more potent than the physical research material. The perceived value of research material e.g. blood and urine by participants was mainly due to cultural and religious beliefs in some instances.

4.3 Broad Consenting and Re-consenting to influence Genomic Data Sharing Practices

Broad consenting views were weighed against the views of re-consenting to understand the ethical aspects affecting data sharing in research. The CHVs staff mobilizing the research participants maintained that re-consenting would be cumbersome and could lead to research fatigue. A participant was quoted saying.

> *"We would appreciate the use of broad consent from the onset and the consent to be adequately informative to allow for continuity of research, as re-consenting strains the process of research."* **(Interviewee 11, AWI-Gen participant)**

Research experts were critical of the over-reliance on broad consenting methods. The use of broad consenting methods was said to be on the '*edge of ethics'* by a respondent in data management. The researcher was quoted saying,

> *"The broad consent is a thin line to walk. Regarding personal data, it implies that collected data can be used in a way that is unintended; hence it could be unethically applied."*
>
> ***(Interviewee 11, researcher)***

Study respondents noted that researchers are inherently human, and the use of data, even if governed, is at risk of being unethically used if the consent given in the first place was broad or unspecific. Broad consent places no barriers to the extent of genomic data usage and could compromise its ethical usage if shared with commercial entities. The concept of broad consent in research is dwindling though consent that is not specific in sharing and extrapolative research can be considered as 'broad'. Even though participants would require re-consenting modules even where "*the need of sharing"* may be urgent, as put across in the data collection tools. The patterns and means of going back to participants were appreciated as being logistically tasking. The interviewees, basically in favor of broad consent in genomic data sharing, demonstrated utmost trust in the research institutions they had interacted with such as the African Population Health and Research Center (APHRC) and KEMRI (Kenya Medical Research Institute).

The research also identified the knowledge gaps in the intricacies of the different types of data collected in the AWI-Gen collaborative project. Participants recalled verbal interviewing and bio-data measurements more vividly than the genomic data collected. Data collection through interviews and biodata is more remarkable to participants than the other forms of data. The genomic data, therefore, is not realizable in its full extent by AWI-Gen participants as a matter that can affect research exponentially. Some field researchers and CHVs could not distinguish the different forms of data collected in the field, presenting challenges in the communication strategies that could be used to explore the innovations of genomic research to concerned participants in lieu of complimentary data collected. Figurative language and demonstrations were effectively used to transfer knowledge to lay participants, especially on the value of genomic research data. This strategy revealed the need for creativity in conveying the technicality of genetics through use of anecdotes, diagrams and figurative language.

The distinguishing of biodata, i.e. (screening tests) and their goodwill, were overly appreciated due to therapeutic misestimating. *Therapeutic misestimation* is described as the overestimation of benefits that a study can have or the underestimation of potential risks associated with a study by the participants. The misperceptions were mainly due to an over-appreciation of the health-motivated initiatives and a limited understanding of the genomic contexts of research. Such interviews would steer off topic with sensitivities and focus being derailed to the health challenges they were experiencing presently in the given communities. As one interviewee put it: -

> "*The use of (genomic) data obtained from us should at least be used to provide subsidies on chronic ailments since they are costly to us. According to the data collected from us as a population, it would be better if involved participants are followed up to be offered treatment in future… I have a neighbor who is a known diabetic, and the challenge of him acquiring treatment would require intervention from organizations involved with research such as the one you represent."*
>
> ***(*Interviewee 14, Participant's Spouse*)***

4.5 Views on Genomic Data Sharing Policies

The genomic data-sharing policies and practices have been drawn on the General Data Protection Regulation (GDPR) Act formulated for European Union (EU) Countries. The policies have a dynamic international approach, but most ethical intricacies come from local perspectives and policies. In Kenya, the Public Health Data Act, enacted in 2019, is used to fortify the rights of individuals to privacy and personal protection of personal or personified data. The use of health

data is increasingly adopted for regular use in clinical practice, potentially acting as an exposure to harmful practices in data sharing and usage. The Data Protection Act (DPA) introduced new data standards to categorize personal clinical data as sensitive when it divulges personal data. In this current study, the research experts were able to demonstrate an understanding of data-sharing policies in genomic research. Field research workers were not expressly knowledgeable of data-sharing practices and policies, and they presented them as vague concepts. For most field workers the repertoire of their assignment did not require handling genomic data but they had some basic exposure to genomic research objectives. The ethics of professional research were observed by participants and researchers of AWI-Gen. For example, researchers were aware of the principles of confidentiality and privacy as it applies to research practices in the field. One participant had termed the data as sensitive, saying,

> "*It is essential that the data be distributed to the right people. It should not be shared by roadside methods.*" **(Interviewee 4, Field Worker)**

The following was quoted from another participant with similar concerns,

> "*You can only share data with the people who you trust…"* **(Interviewee 7, *CHV*)**

Data sharing through drafting Data Use Agreements was explored, with participants involved. The participants cited satisfaction from ethically drafted Data Use Agreements that could be inclusive as they required re-consenting, if need be, in the respective scenario where the data were to be shared explicit of their initial consenting. The fieldworkers involved with data handling demonstrated an

understanding of the ethical principles of confidentiality and anonymity. The participant data were scrambled in the field to de-identify it from the participant, and they were made to understand the ethical reasons for this mode of data protection. Restricting data sharing through non-disclosure agreements was appreciated as a protective measure while still being interpreted as a data management style that limits the spread of research knowledge.

4.6 Formulation of Data Use Agreements

The involvement of Data Use Policies within the organization was appreciated by the research team involved with data management. A researcher involved with Data Management (Interviewee 2) justified the reasons for having Non-Disclosure Agreements (NDAs) within the field. The researcher was aware of data sharing without identifiers to protect the data from harmful use. The interviewee noted that;

> "*There are data sharing policies on which data can be accessed and which cannot be accessed by study partners… the elaborations of such clauses are detailed before the beginning of the research. These regulations are highlighted in the Data Protection Act*."
> **(Interviewee 2, Researcher)**

4.7 Views on Sharing AWI-Gen Genomic Data with Research Institutions

A field worker involved in the AWI-Gen study thought that genomic data could be extrapolated into another research. The field worker expressed views that some companies could widen their research knowledge by doing what could not be done by the AWI-Gen Project. Researchers expressed a liberal perspective regarding the sharing of genetic data with commercial entities,

advocating for the practice of data de-identification in order to prevent the disclosure of personally identifiable information. The AWI-Gen genomic data were not open for sharing with commercial entities, and this was expressly detailed in informed consents of participants and Data Use Agreements between partners involved in the research. Interviewee 2, a participant, said, "*Reasons for data sharing may be diverse… in sharing personalized information, the understanding of each involved party may vary*". The denoting of the different multi-disciplinary understandings warrants different approaches when drafting Data Use Agreements. Overall, the participants in this research showed a sufficient level of willingness of cooperation with commercial entities. However, this raises the need for research ethicists to develop guidelines and protocols for the sharing of data with commercial entities.

Most participants were in favor of data sharing with other research institutions demonstrating enough trust between research institutions. The ethics of researchers was not in question in any stage of data sharing especially where the research was exclusively non-commercial. The demonstrated trust seems to stem from previous community engagements of research institutions. The participants did not distinguish the ethical practices of researchers within the same field and this reinforces the need for robust Ethical Review Boards and Committees to ensure there are no unethical gaps between institution practices and data sharing. Some researchers made it clear that extensive sharing of research data was not practical even between research institutions as most researchers who bear the cost of research data collection end up with governance and propriety responsibilities.

4.8 Views on Data sharing with Commercial Entities

The data tool sought participants' views regarding sharing genomic data with research institutions while sensitizing on commercial healthcare entities. Use of genomic research was restricted from sharing in the case of the AWI-Gen project as laid out by the researcher's privy to the consent of the process. Participants demonstrated liberal views regarding sharing data, with a few (only less than 20%) being conservative about data sharing with commercial entities. One researcher cited the need to perform genomic research in the pharmaceutical industry to demonstrate drug interactions with specific population groups. The sharing of genomic data is more effective if taken up by commercial companies able to cover the resource gap between non-profit making entities and commercial research involved with innovative therapeutics and pharmacogenomics. The researcher gave the following remarks,

> *"Yes, it is okay to share with other research companies, especially drug manufacturers, to understand different genes and their interactions with pharmaceutical drugs. It is possible to later develop specific knowledge aspects to the people with the right data in mind."*
>
> **(Interviewee 1, Researcher)**

The sharing of data with commercial companies was taken with subtle risks across the participants interviewed though this did not affect their views on the possible benefits this could bring. The genomic data is lauded as valuable when shared and most participants linked this to a commensurate benefit on their part. One participant was quoted saying that there must be something in exchange if genomic data is shared with commercial entities as this would require, they benefit also from research. The participant used the backdrop of economic and health challenges that were experienced by community members and their appreciation for positive socio-economic impact of research if attained by researchers. Researchers

involved with AWI-Gen were explicitly aware that research data was restricted from sharing with commercial companies mainly due to exploitation and unprecedented use according to terms and regulations stipulated during consent. However, a collective few were for genomic data sharing with commercial companies citing reasons such as pharmacological advances and socio-economic boosts.

Previously engaged participants of the AWI-Gen project were looking for transferrable benefits if genomic data were to be shared with commercial entities. Some demonstrated good faith in the commercial entities, terming them as '*able to assist them in getting medication*,' even though health bettering goals and modes of sharing genomic data and their reciprocation were not explicitly clear to the participants. An AWI-Gen participant in the Viwandani community expressed a willingness to consider the sharing of genetic data with commercial organizations, under the condition that the researchers receive monetary recompense in return for any financial gains derived from such sharing. Interviewee 14, a participant, described sharing genomic data with commercial entities as a sound objective "*If it could ensure something in it for them*."

4.9 Chapter Summary

The AWI-Gen Project involved several different forms of data sharing. The process was managed by a research team and field workers acting as data 'scramblers,' relaying raw data to the researchers, who then analyzed the data along with their findings. The field workers were able to change personal identifiers, as well as indirectly share information with commercial entities using anonymized codes. Perceptions of ethical issues were diverse and contradictory regarding sharing genomic information with commercial entities. Contrasting participants' statements that refer to ethical considerations in the handling of personal information were put forward while discussing what is morally permissible to do with genomic data.

CHAPTER FIVE

DISCUSSION

5.1. Introduction

This chapter discusses the key findings of this research in relation to the existing literature. It highlights findings reflecting existing or new issues in the literature. It explores the preferences of genomic research (AWI-Gen) stakeholders in genomic data sharing with commercial entities while observing values of trust, confidentiality, and consent practices within the field of genomics.

5.2 Socio-Economic Values of Genomic Research Data

The use of big data analytics and technology has made considerable changes to how data is used, accessed, analysed, and shared between health professionals and institutions. Privacy and confidentiality on the broad spectrum of public health data is an already existing concept. However, innovations in health and disease alleviation could take place through the extensive use of genomics across dynamic health-industry players. The statistical power for Genome Wide Associated Studies (GWAS) is improved through genomic data sharing (Yin, 2020). The imperative for the sharing of genetic data underscores the importance of examining ethical narratives around genomic data sharing in order to provide guidance on the ethical principles that should govern such sharing. Genomic sequencing has enabled the identification of genetic roots of diseases. Genome sequencing costs about $800 to $1200 to perform for a single individual; this presents an economic challenge in aggregating genomic databases especially in Low- and Middle-Income Countries (Marshal et al., 2022). Commercial entities are capital resourced and have skilled human resources to steer the direction of genomic data aggregation when ethical regulations of genomic data sharing are used. Funded programmes may not exponentially work on genomic innovations as most objectives of genomic research are specific and bound by allocated time and budgets.

Despite unaided regulatory framework and shadowy intents of commercial entities, there is a demand for genetic data sharing by most healthcare industry players. Researchers use gene chips or DNA chips to gather wholesome genomic information that might point out disease links and specific targets associated with diseases. In an ethical overstep, Wellcome Sanger Institute recently got backlash when it ordered 75,000 gene chips from a repository lab without partners' consent (Stoksad, 2019). Such moves show a possibility of unethical genomic data sharing from partnered projects in similar contexts. Instances such as the one mentioned provide evidence that a market need for genetic data exists within commercial enterprises, even in the absence of ethical considerations. To protect the interests of end-users and to ensure that there is bridging of resource gaps in genomic translational research, ethical frameworks should aim for commercial engagement under goals seeking to manage genomic data not as a potential monopoly of researchers but as a partnership with commercial entities of interest. In such delicate partnerships, the contribution of genomic research data by researchers could be invested in by commercial entities promoting infrastructural benefits of in-aligned incentives e.g. financing of biorepositories and capacity training in genomic studies (Marshal et al., 2022). Genomic data-sharing arguments in LMICs such as Kenya are more objective and geared towards the interplay of stakeholders and their interests than individual persons and single stakeholder perspectives (Jao et al., 2015). The interplay of stakeholders in data sharing is well explored through qualitative data analysis methods. This study began with the backdrop of participant experiences, especially those of AWI-Gen Phase I and II, which stakeholders could recall at ease. The participants were receptive to the programme and expressed satisfaction with the research. The participants were expressly motivated by the project being of direct therapeutic benefit regarding screening and gaining knowledge on their health; this contradicted the finding of Marshall et al. (2022), who established that the sample

population involved in a population-based genomic study in the United States found the participants to be aware of their expected direct benefits. The participants could identify with the research goals as 83.5% of a genomic population study participants agreed that "*there may not be a direct medical benefit to me from my participation in the research study*," (Jao et al. 2015). In this current study, however, it was observed that there are inconsistencies in the understanding of research motivations of genomic research participants in Africa. Participants in the Kenyan AWI-Gen studies were optimistic to an extent that they therapeutically misestimate the studies overall objectives.

The participants in this current study also opted for genomic data sharing with commercial entities to ensure the availability of pharmaceutical drugs and accessible healthcare benefits, while there was no laid out framework for achieving this endeavour. These desires were steered by socio-economic health challenges such as unaffordable drugs and lack of access to quality and affordable healthcare. The participants did not cite reimbursement money as an influence in the AWI-Gen project, though optimism of positive healthcare impact emanating from the project was displayed. The motivations of research participation in the AWI-Gen study could not be motivated highly by the issuance of reimbursement as was the case in the Marshall et al., (2022) study. Some participants could not draw different agendas of commercial entities as they were far-fetched to them and research institutions; the financial factor did not present as a matter of contemplation or concern to them, as it did the potential benefit, they stood to gain in genomic data sharing. This re-enforced the need for community engagement in future interactions of Research and the Health service industry where the mutual trust and reciprocity could be built on more platforms other than financial re-imbursement (Koln, 2000).

Participants who were CHVs and had attended formal or informal training sessions scheduled within the project identify with what they had learned. The learning was meaningful in discussing meeting research objectives. The development of autonomic views of genomic data sharing with commercial entities was attributable to prior learning or engagement made by researchers. It is agreeable that the continuum of community engagement objectives requires long-term engagements to reflect ethical views that resonate with communities involved with genomic research over matters such as genomic data sharing, which are highly dynamic and evolve over time (Tindana et al. 2015). The field workers had a clear recollection of the community engagement approaches that were promoted by the CE-BioGen project, as well as the effortless establishment of amicable relationships with the participants.

The appreciation of genomic study objectives was found to be low. Participants readily identified with verbal and biometric data collected more easily than genomic data. Field researchers and participants collectively reported an under appreciation of genomic data potentiality. Researchers' perspectives were inferred from the limited adoption of genetic data perspectives throughout discussions and dissemination of research findings. Data analysts, for example, could not link *genomic* data to healthcare transference from the AWI-Gen research project module. The training acquired by researchers and community health workers was identified as a significant factor in their acquisition of knowledge and skills in conveying genomic aspects of research. The significance of sharing genetic data cannot be fully recognized without a proper appreciation for the value of genomic information. On the other hand, participants denied having problems relaying information associated with informed consent to peers and family members going to show their ability to carry out informed consent.

Two participants involved in community health work and the participation for AWI-Gen could remember that they were involved with "*mafundisho*," which is Swahili for teaching (especially in the genomic aspects of the study). The genomic understanding of the participants through Community Engagements methods was found to be appropriate in building narratives that inform their ethical standing. Tindana et al. (2017) points out that successful CE's nature depends on *"dedicated funding to promote sustainable relationships with relevant communities that supports open science"*. The narrative ethics of research is considered to be well balanced when it emphasizes the advantages of genetic data sharing, while also critically assessing the potential hazards that may arise for both the community and the individuals who contribute to the creation of value during the course of the study. One can say that narrative ethics accounts for openness and transparency.

The response of disease-focused genomic care is fast and more extended than human genomic research to lifestyle and rare diseases. Pathogen genetics responses, e.g., the responses found in Ebola, COVID-19, and malaria, keep making strides, while those focused on lifestyle illnesses are inching slowly. Human and infrastructure capacity development coupled with dedicated funding and political will can serve as "critical elements of success" in human genomics in Africa (Kamp et al., 2021). Globally 3.5%-5.9% of people are affected by a rare disease, while the increase in Body Max Index (BMI) has tripled in middle and low-income countries in the last four decades (Asiki et al., 2017). The increase in these diseases would indicate a demand for insurance and translational genomics in modern-day healthcare management within localities of those most affected. Researchers rely on financial support to carry out their work. Therefore, it is beneficial to consider establishing collaborations with corporations in order to safeguard the long-term health interests of communities. This necessitates political determination and the enactment of supportive laws to address the ethical requirements and concerns of all stakeholders

involved in the communities being studied. (Kamp et al., 2021). Forming detailed partnerships with corporate entities would identify the responsibilities to be shared (Marshal et al., 2022).

In order to formulate development of public policy, the study aimed to utilize the methodology of narrative ethics. Narrative ethics demonstrates efficacy in the context of medical research. The utilization of principlism as a normative ethical framework fails to adequately delve into the multifaceted ethical considerations encompassing beneficence, autonomy, non-maleficence, and justice across several disciplines (McCarthy, 2003). Principlism was not observed in the participants' views, as their views reflected individualized motives and understanding. A participant seeking autonomy could not relate similarly to one who sought beneficence from research, even though each expressed a particular ethical principle. Views were widely dynamic, especially on sharing *'personal genomic data'* because this was based on one's beliefs and understanding of ethical genomic research phenomena. Some interviewees, unsure whether genomic data sharing with commercial entities was ethical, formed opinions based on the relativism of anecdotes or hypothetical scenarios they have come across. The technique demonstrated the uniqueness of narrative ethics and its effectiveness in constructing themes of qualitative research. For a shift in Participant Led Research in human genomics in Africa, consenting, genomic data usage, and genomic data material management could be restructured to reflect critical issues associated with research participants (Dorfman, 2015). A re-consenting module that could be a method for tracking participants and gaining approval for data sharing was found unfeasible due to Industry Led Research incentives. Creating a space for future contributions by participants to research ethics should be explored using the insights and needs of the participants to motivate ethical genomic data sharing.

An Investigator Led Research (ILR) is likely to have motives solely driven by profit in healthcare and clinical use of genomic data (especially if commercial healthcare entities are involved). Such a scenario could present clashes over the beneficence and justice of participants in genomic research data usage by other players in the health sector. For example, applying broad or unspecific consent as an efficient consent model only due to Industry Led Research (ILR) would be potentially unethical as it could shadow the interests of research participants.

Data managers affiliated with the research project in Kenya cited ILR standards that restricted genomic data sharing with commercial entities, such as the General Data Protection Regulation (GDPR) and the Data Protection Act 2019, despite not appreciating the intricacies and potential benefits of genomic data exploitation. Citing the clauses restricting data sharing with commercial entities while protecting the study's sample population could stifle research and subject it to a "straightjacket" (Dorfman, 2015). Despite arguments for genomic data sharing, Jao et al. (2015) stood to satisfy the need to understand genomic data sharing as complex, requiring researchers to narrow the propositions to *"who shares what information and how"*. The participants formerly involved with the AWI-Gen Project were not extremely conservative of genomic data-sharing as the researchers. However, most researchers' views were informed by avoiding potential risks according to their experience while observing ethical protocols when conducting genomic research.

The findings from this current study suggests that there is a need to boost mentorship, capacity building, and local research sector protection to ensure a flow of data that promotes equitable research and development of health sectors in both commercial and non-profit-making entities. Collaborative efforts of researchers and commercial entities would prevent widening gaps in the field of genomic research in LCIMs and developed countries. The establishment of integral data frameworks within local communities should prioritize the cultivation of collaborative

relationships with researchers. This can be achieved by focusing on the development of research competency, promoting transparency, fostering inclusivity, and facilitating the dissemination of research findings. (Claw et al., 2018).

The employment of relevant research capacity development prevents global research inequities, even for commercial and non-profit research entities. Some protection mechanisms, such as embargo periods for data release could be used to prevent data being immediately released before local communities could make head or tails of it (Glenna et al. 2011).

5.4. Appropriate consent models for data sharing with commercial entities

The consenting done in the field during genomic data collection could include clauses allowing for sharing aggregate data to identify the determinants of genomic frequency as a research toolkit, as this poses less risk of exposure and personalization of data. There are public research tools with platforms such as gnomAD, AVGD, and ClinVar that can extend data availability even with research institutions and companies (Landrum et al., 2016). Lumaka, Carstens, et al. (2022) expresses the need for educating African research participants on the meaning and value of sharing genomic data that can be aggregated and checked for frequency even in non-personified data. The genomic data could aim for a specific interest as it is required that the shared data be inclusive of a dynamic and proliferated society to ensure that the target populations are not misrepresented. '*The value of data is in its sharing'* was put across by one member linked to data management in the AWI-Gen research team. Data collected should be representative of sample population dynamics for it to be sharable; this means that researchers should employ statistical advantages to represent sampled populations accurately. Research strained to a specific community and geographical region can fail to be valuable if it does not encompass variability and differentiation adequately. Genomic data

value before research should be considered by researchers and participants alike to inform on its clinical use, especially in meeting research needs or healthcare research gaps. Understanding the essence of genomic data by stakeholders can increase its value even in both research and commercial settings was identified as highly likely to cause exploitation where genomic data was to be shared by commercial entities. Re-focusing on re-consenting is more ethical if genomic data or material is to be used in alternative ways than previously expected.

The participants were startled (both in expression and remarks) by words such as 'commercialization,' 'commercial use,' and 'corporations.' From the onset, the term commercialization could be mentioned in informed consent (Marshal et al., 2022), through a standardized language bordering on economic gains attributable to genomic research. As noted in the interviews, using the word 'commercialization' usually brings about differences in perceptions. The term came across as potentially exploitative to participants and could elicit reactionary views based solely on perceptions mired by the delivery language. The elaboration of commercial underpinnings, such as *pharmaceutical companies' drug trials* and *genomic databases for private healthcare innovations*, were received better than broad terms associated with commerce. Therefore, the indication of commercialization or commercial companies involved with research should not be used without adequate meanings and contexts being inferred.

5.5. Chapter Summary

The participants and researchers involved with AWI-Gen were consistently aware of the implications of genomic research in terms of its benefit and risk. Over-reaching potential benefits that could accrue from genomic research was a result of therapeutic misestimating of

participants. Researchers on the other hand were ethically attuned to the requirements of the research even when unprecedented occurrences were possible due to their experience. The discussion of commercial genomic data sharing was approached with care yet it raised emotions of beneficence across both researchers and participants of AWI-GEN. Participants require protection mechanisms to ensure no breeches are made and researchers did not leave this out.

CHAPTER SIX

6.0 SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

6.0 Introduction

This chapter summarizes the entire study through four thematic areas: summary of the study, study findings, conclusions, and recommendations.

6.1 Summary of the Study and Findings

The study was conducted to gather perspectives to inform the ethical sharing of genomic data with commercial entities, using the AWI-Gen collaborative study as a case study. The study gathered views from research experts, field researchers, and participants involved with the AWI-Gen project. The views came from informed people and people uninformed to research policies in the AWI-Gen project. The genomic data-sharing ethics matters were molded from narratives to formulate narrative ethics.

The following findings were made from the research: - (1) there are benefits that could be gained from sharing data with commercial institutions and this could bring positive socio-economic impacts if transference of benefits as a policy is enforced. Translational genomics from most private funded companies can instigate research benefits for some rare illnesses that are not prone to ease of management by many locals within the communities of research. (2) The recommendations of consenting genomic data sharing would fall between tiered consenting and re-consenting as both are publicly supported although for unprecedented occurrences such as hacking and data leakages in multiple handlers of data only remedial measures can be implemented. (3) The guidelines fostering genomic data sharing are all embedded in values of

transparency and control from research institutions. In some instances, the community heads would give a blanket view on the moralistic approach of data sharing but for individual genomic data and emergent issues of research, participants were requiring of re-consenting and a share of control of the handling of their research material.

6.2 Study Conclusions

The genomic data-sharing practices in the private sector were found to be welcomed by the critical stakeholders interviewed. Genomic data-sharing practices views were backed by the fact that commercial entities could ensure adequate resource and capital allocation in research gaps yet to be exploited. The advancements obtained from genomic data sharing could provide transitional milestones in research (Ramsay, 2022; Byrd et al., 2020; Marshal et al., 2022). Participant sentiments were motivated by transparency, control, proximity to fellow participants' and goodwill. The researcher well observed the contributory spirit to research in the respective communities. For those who were complicit with the objectives of the African Population and Health Research Center (APHRC) in other research projects, their views were backed by the societal contribution they had experienced with APHRC research projects. Some participants were motivated by the background knowledge of the values of APHRC and seemingly trusting their research protocols.

Participants who voiced their concern about research transparency required dynamic methods of consenting that would contribute to their overall understanding and making informed choices in genomic data sharing. Some members were responsive to maintaining control of their data and samples regarding data sharing citing concerns such as the relay of feedback and inclusive,

participatory involvement.

Individuals residing in tightly interconnected communities within densely populated areas exhibited a sense of vigilance regarding the dissemination of information to unintended recipients, even when shared with individuals outside their immediate community. This heightened caution can be attributed to the close physical proximity of their residences, particularly among participants in genomic studies who face socioeconomic and health-related difficulties. The perceived likelihood of information being disseminated to neighboring individuals and other members of the community appeared immediate to the individuals in question, while lacking justification for such concerns. The commercial entities were appreciated for being able to offer new insights into research, given their economic capabilities. However, the participants involved in AWI-Gen were concerned with benefit sharing in instances where the genomic data is shared with commercial entities. The interviewed researcher noted the unfounded perceptions that riddled the community. The perceptions of transferable economic benefits recurred severally as some interpreted research as a stimulus accessing health services (which is an economic burden to most individuals in Kenya) and affects them socio-economically.

6.3. Contribution to knowledge

Given the limited empirical evidence on the perspective of stakeholders on data sharing with commercial entities, this study adds to the academic discourse on the ethical dimensions of data sharing, contributing knowledge that can inform future research endeavors. It offers a comprehensive examination of the ethical landscape in the context of genomic data sharing with commercial entities.

6.3. Recommendations

The study findings realize the benefit of proper Data Management between collaborative genomic projects. The presence of multi-disciplinary stakeholders in Genomic Wide Associated Studies (GWAS) requires the incorporation of ethicists to enable morally robust practices. Despite the protective policies, the interviewees expressed goodwill toward genomic data sharing with commercial companies, provided risk and benefit sharing is mitigated. The participants were optimistic that sharing genomic data with commercial companies can benefit their healthcare needs. The exploration of ethical genomic data sharing is yet to be done extensively as the various relation mechanisms of genomic data users cannot be compiled with minimal research.

The users of genomic data can come from different disciplines and backgrounds, and this identifies the need to adopt strategic partnerships in genomic research. Genomic research would require a set pool of resources for efficiency in both the public and private sectors. Research entities such as APHRC can influence strategic partnering with industry players for research purposes. In such circumstances, developing Data Use Agreements that foster sustainable and legally sound partnerships between researchers and public and private healthcare service managers in both commercial and non-profit settings would be prudent.

6.3.1. Recommendations for data sharing policies

Well-drafted legal Data User Agreements can be developed with the assistance of expert ethicists to address ethical concerns in the sharing of genomic data. For instance, when creating gene chips and data chips for genomic databases intended for use in commercial healthcare, it is advisable to involve key stakeholders associated with research in the decision-making process.

Researchers have the option of monopolistic practices to genomic data or partnerships that align the incentives of researchers and commercial healthcare companies. The partnerships of researchers and commercial entities could seek shared responsibilities and benefits derived from data sharing.

Words likely to elicit unwarranted or emotive reactions can be reduced as policy drafters and ethicists seek to standardize them (Mohamed & Syed, 2022; Caufield et al., 2014). Definitions of commercial players in genomic data sharing can be described precisely to prevent legal loopholes and to form policies that can be used interchangeably across continents. Harmonizing vocabulary used in the genomic data-sharing industry would prevent ethical debates among stakeholders.

6.3.2. Recommendations for data sharing practices

Short Term Strategies: The ethics of data sharing could be explained better with other narratives in relative community regions. The use of narrative ethics to explain data sharing is found to be grounded on the immutable principles of medical ethics of beneficence, malfeasance, autonomy, and justice. Despite under-explored narratives from participants with low exposure to genomics, the foundation of genomics and its basic principles need further probing on participants within the region to enable them to give valuable contributions to the narrative ethics in question (Ramsay, 2022). The study shows the requirements of adaptiveness of re-consenting techniques or tiered informed consent to allow for future growth in genomic research. Reviewing highly informative consenting techniques can explore knowledge gaps between participants and researchers while working to bridge them.

While beneficial and readily applicable, field screening tests should complement the themes of genomic research in a fashion that does not diminish genomic concepts to the participants

involved. The differences in understanding, especially in Low and Middle-Income Communities (LMICs), requires strategic and creative approaches to diffuse the elements of genomic research to end-user communities. If informed appropriately on the research subject, the end users can give contributive pieces in narrative ethics, especially in the ethical sharing of genomic data sharing with commercial companies.

Long Term Strategies: There is a need to boost mentorship, capacity building, and local research sector protection to ensure a flow of data that promotes equitable research and development of health sectors in both commercial and nonprofit entities. The employment of relevant research capacity development prevents global research inequities, for both commercial and nonprofit research entities. If ethically streamlined, sharing genomic data with commercial entities could ensure that research technology and skills gaps are bridged and equity in research resources is achieved. Continuing research through socially trusted institutions protects values such as transparency and mutual trust which boosts growth of research activities within the region.

6.3.3. Recommendations for future research

Short Term Strategies: Future genomic research could invest in dynamic consenting as an initial ground setting to motivate data sharing with commercial entities. The investment would look at elaborating certain technicalities of genomic data sharing during consenting and expounding on concepts the participants may find difficult to understand. Some of the risks of exploitation or innovation that shared genomic data would have are not entirely fathomable at the moment. Future research could commit to informed consent and participant motivation in the research-engaged communities to empower them to form well-thought-out ethical evaluations. Understanding what participants understand in genomic research data would improve the autonomic process of genomic data sharing, which is an ethical priority for research participants.

Long Term Strategies: The reviews of Research Ethics Committee could have stipulations conducive for genomic data sharing especially to promote Beneficence in regions that have knowledge disparity while still ensuring there are no loopholes for unethical manipulation of Genomic Data Use and Sharing. The oversight of these review bodies can ensure that there is fostered trust and dependability of genomic data to promote equitable benefits of research to the involved stakeholders.

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Appendices

Appendix 1: Focused Group Discussion Guide

Study Title**: Ethical Issues in Genomics Data Sharing with Commercial Entities: A Case Study of the AWI-Gen Collaborative Project**

Kichwa cha Mradi**: Uchunguzi wa washika dau wahusika kuchambua maono yao ya ugavi wa data kwa mashirika ya kibiashara: Ukihusiha muungano wa AWI-Gen**

FGD GUIDE FOR PARTICIPANTS OF AWI-Gen.

Introduction

- Welcome the participant and briefly describe the objectives of the study
- Review the Study Info Sheet & provide a copy of the Consent Form for signature
- Outline the format of the interview

Section A: Background of participants

Participant ID	**Age**	**Education**	**Occupation**	**Religion**
1.				
2.				
3.				

4.				
5.				

Section B: Experiences with the consent process of AWI-Gen

Uzoefu na hatua za kupokea kibali ya kushiriki kwa AWI-Gen

1. Would you remember the consent process of how the AWI-Gen study was done?

   Je, unakumbuka jinsi ambavyo ulipeana ruhusa ya kuhusishwa na utafiti wa AWI-Gen?

2. Should the use of genomic data and material from the research be used from broad consenting or dynamic consenting?

   Je ungependelea ruhusa ya kijumla au ya utumizi wa data ya genomics na bidhaa za zinazotokana na utafiti zina

3. What suggestions would you make to improve the way you would like the materials of research and data from research to be managed?

   Ni mapendekezo gani unayoweza kutoa ili kuboresha njia ya kusimamia bidhaa za utafiti na data inayotokana na genomiks?

Section C: Views on Participation

Maoni kuhusu kushiriki

4. Why did you agree to participate in the AWI-Gen study?

Kwa nini ulikubali kushiriki katika utafiti wa AWI-Gen?

5. How did you feel about participating in the study?

Ulihisi vipi kushiriki kwenye utafiti?

6. What have been the benefits of participating in the study? Probe for any risks they might be aware of in participation.

7. Is there anything you will like to add to your participation in the study that I have not asked?

Kuna kitu kingine ambacho ungependa kuongezea kuhusu kushiriki kwako kwa utafifi ambacho shatujazungumzia?

Section D: Views on Ethical data-sharing with commercial entities

Maoni kuhusu ugavi wa data na kampuni za kifedha

8. Would there be a benefit to sharing genomic data from participants with commercial entities?

Je, kuna manufaa gani ya ugavi wa data ya genomiks kutoka kwa washirika kwa mashirika ya kifedha?

9. How would you feel when your genomic data were shared with other researchers and non-profitable institutions? Implore values of discretion, autonomy, and justice.

Je,unaweza hisi vipi data yako ya genomic iki gawiwa kampuni za utafiti na makampuni yasiyokua ya faida? Chambua wanavyo onelea kuhusu usiri, kujiamulia na haki.

10. What do you believe are the benefits of genomic data sharing to the community? Are there risks involved with genomic data sharing from communities?

Je, data ya genomics ikisambazwa iko na umuhimu gani kwa jamii? Kuna adhari zipi zinazoweza kutokana na ugavi wa data ya genomiks?

11. How does ethical data sharing minimize risks to a community? Probe for the effect on society.

Ugavi wa data kwa njia ya haki na usawa una husu jammi kivipi? Dadisi: Uhusiano wa ugavi wa data kwa jamii?

12. Do you think rare personal genomic data from certain individuals are to be shared with commercial companies? Should the participants be recognized for their contribution?

Maoni yako ni yapi kuhusu kugawia data ya kibinafisi na yakipekee ya watu ambao wana dalili za kuugua? Unaonelea kwamba watu hawa wanafaa kurudishiwa mkono wakihusika kwa utafiti itakayo tumia data hio?

13. What is your take on data-sharing techniques that provide genomic data on open platforms e.g. websites? Do you think it preserves confidentiality and anonymity?

Maoni yako ni yapi kuhusu ugavi wa data kwa njia ambazo zinawezesha watu wengi kufikia data hio k.m tovuti za utafiti? Je unaonlea kua njia hizi zinahifadhi usiri na kutowatambulisha wahusika?

Section E: Policies of Data-sharing

14. How would you want your genomic data obtained from the AWI-Gen project to be handled? Probe for cultural appropriateness in policies such as non-disclosure agreements NDAs and Broad Consenting.

Je, ungetaka data inayopatikana katika itafiti huu wa AWI-Gen utumike aje? Chambua kuhusa kutofichua data ya wahusika na ruhusa ya kijumla kwa utafiti

Section F: Recommendations and closure/ Mapendekezo

15. Is there anything you would like to add to data sharing in the field of genomics?

Je, Kuna kitu kingineungependa kuongezea kuhusu ugavi wa data katika genomics?

Thank you for participating in this discussion/ Asante kwa kushiriki kwenye mazungumzo

Appendix 2: IDI GUIDES

Interview Guide – IDI-Study coordinators, Researchers & field assistants

Study Title: **Ethical Issues in Genomics Data Sharing with Commercial Entities: A Case Study of the AWI-Gen Collaborative Project**

Kichwa cha Mradi**: Uchunguzi wa washika dau wahusika kuchambua maono yao ya ugavi wa data kwa mashirika ya kibiashara: Ukihusiha muungano wa AWI-Gen**

[Target Group Study coordinators; researchers and field assistants]

Introduction

- Welcome the participant and briefly describe the objectives of the study
- Review the Study Info Sheet & provide a copy of the Consent Form for signature
- Outline the format of the interview

Section A: Background of the Interviewee

Interviewee ID	Level of education	Length of service	Genomic training

Section B: Knowledge/Experiences with genomic studies for lay persons involved in AWI-Gen

Habari za maarifa na ujuzi unaotokana na uchunguzi wa genomics kwa wahusika wa AWI-Gen ambao hawajajihusisha vilivyo na genomics

1. Can you please tell me about the genomic research study you were involved in? *Tafadhali nieleze kuhusu mradi wa utafiti wa genomic ambao ulihusishwa?*

    a. Probe for H3Africa Study: what is the study about? What does it involve? Why was the study important? What was your role?

    Dadisi kuhusu mradi wa H3Africa: Mradi ilikua kuhusu nini? Ina husisha nini? Kwa nini huu mradi ni muhimu? Jukumu lako ulikua upi?

2. Did you encounter any issues explaining the study to research participants and staff members?

Je, umekumbana na matatizo yoyote ukielezea juu ya mradi washiriki na wafanyikazi?

a. Which aspects of the study were problematic?

Ni sehemu gani zinazojumiusha mradi huu yalikua na tatizo?

3. As a participant did you understand the purpose of carrying out the AWI-Gen research project?

Je wahusika wanaelewa sababu za kutimiza utafiti za mradi wa AWI-Gen?

4. Did you understand the type of data that was derived from the involvement you had with the AWI-Gen collaborative project? i.e.
   a) Data shared verbally
   b) Biodata
   c) Genomic data

Je unaelewa aina ya data ambazo zilitokana na kushiriki kwako kwa utafiti wa ushirikisho wa mradi wa AWI-Gen? yaani

a) Data iliyotokana na ulichonena katika uchunguzi

b) Data iliyotokana na vipimo vilvyo fanuyika katika cliniki

c) Data inayotokana na genomics

Section C: Participants' understanding of genomic data sharing policies and practices

Mfumo wa kuelewa njia ya kufanya ugavi wa data wa genomics na mienendo yake

5. Are you familiar with any policy documents concerned with the practice of data sharing?

   Je! Unajua hati ya sera yoyote kuhusu mienendo ya ugavi wa data?

6. Are you aware of the use of genomic data and its application in improvement of human
7. health?

   Je, unajua kazi ya data ya genomics na utumizi wake kwa minajili ya kuboresha afya ya binadamu

8. Are you aware of any of the policies below governing data sharing procedures from research?

   a) Broad consent

   b) Data Use Agreements

   c) Non-disclosure Agreements

   Which policy would you say needs improvement?

   Je, una habari kuhusu sera zinazohusikana na sheria za ugavi wa data inayotokana na utafiti?

   a) Ruhusa ya kijumla

b) Mikataba ya Utumizi wa data

c) Mikataba ya kutofichua data ya utafiti

Ni gani amabyo unaona inafaa ingefaa kuboreshwa?

8. Do you perceive any need for the sharing of personal genomic data obtained from research? Does the urgency of sharing genomic data for research require for re-consenting?

Je, una maono yanayo changia sababu za ugavi wa data wa genomics kutokana na utafiti? Je unaonelea kua umuhimu wa kugawa data kwa mashirika unaipa sababu za mashirika kurudilia ombi la ruhusa wa utafiti?

Section D: Perceptions on the sharing of AWI-Gen data with commercial entities

Maono ya ugavi wa data ya AWI-Gen kwa mashirika ya kifedha

9. What is your perception of data obtained from the AWI-Gen collaborative project being shared with commercial entities that are not entirely for profit such as Research institutions and Universities?

Maono yako ya ugavi wa data kutokana na ushirikiano wa AWI-Gen na masharika ya kifedha ambayo si ya faida ni yapi?

10. Are the previous views mentioned above maintained when AWI-Gen collaborative project data is shared with commercial entities that are for profit?

Maono ambayo umepeana hapo awali yanabadilika vipi ikiwa data ya ushirikiano wa AWI-Gen ina gawiwa kampuni ambazo hua zinazingatia kupata faida?

11. Can you support the views espoused in this section?

Unaweza simamia maono ambayo umepeana katika kitengo hiki?

Section E: Closing Remarks

12. Based on our discussions, what recommendations would you give for addressing the key challenges related to data-sharing genomic studies?

Kwa kuzingatia mazungumzo yetu, ni mapendekezo gani unaweza kutoa kushughulikia changamoto muhimu zinazohusiana na ugavi wa data kutokana na utafiti za genomic?

13. Is there anything that we have not covered that you will like to mention? *Kuna chochote ambacho hatukujumuisha ungependa kutaja?*

Thank you very much for your insightful inputs to this study

Asante sana kwa ufahamu wako kina katika utafiti huu.

NB: Probing on genomic data-sharing will be built on the underpinnings of the participant on genomics.

Udadisi wa maono ya data ya genomics utatumika kulingana na kuelewa kwa genomics.

Ethics & Scientific Review Committee

Informed Consent Form

Study Title	**Ethical Aspects of Genomics Data Sharing with Commercial Entities: A Case Study of the AWI-Gen Collaborative Project**
Investigator(s)	James Waweru, Prof. Paulina Tindana, Dr. Shukri Mohammed, Isaac Kisiangani, Dr. Gershim Asiki
Study Sponsor(s)	CEBiogen
Collaborators	African Population Health and Research Center

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Who can participate? Ni nani anayeweza kuhudhuria?

The persons valid for participating in the research are researchers, participants and community health workers involved with the Africa Wits-IN-DEPTH Partner-ship for Genomic Research (AWI-Gen) in phase I and II.

Watu ambao wanaweza husika kwa utafiti huu ni watafiti, washiriki na wanakazi wa afya wa kijiji waliohusika kwa utafiti wa Africa Wits-IN-DEPTH Partner-ship for Genomic Research (AWI-Gen) katika awamu ya kwanza na ya pili.

Voluntary participation/ Kuhudhuria kwa kujitolea

Participation in this project is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

Kushiriki kwa utafiti huu utafanyika kwa kutaka kwako, kujitoa ama kusitisha utafiti huu hautazuia manufaa zinazotokana na wewe kushiriki vilevile hautatozwa kusitisha utafiti huu.

What is involved in this project? Je utafiti huu unahusu ni nini?

This research is aimed at obtaining information as to the ethical practices in genomic data sharing from Genomic Research using the Africa Wits -IN-DEPTH Partner-ship for Genomic Research (AWI-Gen) as a case study. The study will be facilitated by CEBiogen (Community Engagement in Bio-banking and Genomics) in collaboration with African Population Health and Research (APHRC).

The study's purpose is to get introspective perspectives in the ethics of data sharing from key stakeholders with commercial entities to improve the objectives of Genetic Wide Association Studies (GWAS). Data sharing amongst institutions has been proven to improve statistical power and to reduce sample size issues in GWAS. Despite the benefits of data sharing there are numerous ethical hurdles experienced in fluent data sharing in Africa. This study seeks to identify and address ethical issues pertaining to genomic data sharing with commercial institutions amongst key stakeholders involved with AWI-Gen.

Utafiti huu unahusu kuchukua ujumbe kuhusu maadili ya ugavi wa data ya genomics kutokana na utafiti wa Africa Wits-IN-DEPTH Partner-ship for Genomic Research (AWI-Gen) kama kesi husika. Utafiti huu utahifadhiwa na CEBiogen (Community Engagement in Bio-banking and Genomics) wakishirikiana na African Population Health and Research (APHRC).

Sababu ya kuifanya utafiti huu ni kupokea maono ya undani kuhusu maadili ya ugavi wa data kwa mashirika ya kifedha kutokana kwa wahusika wa utafiti wa Genetic Wide Association Studies (GWAS). Ijapokua kuna manufaa nyingi za kuzingatia ugavi wa data kwa mashirika kuna sababu za kimaadili ambazo zinazuia ugavi huu kutendeka. Utafiti huu utanuwia kutambua na kukabiliana na mambo ya maadili yanayohusiana na ugavi wa data kwa mashirika ya kifedha.

How long will the project last? Mradi huu utachukua mda wa kiasi gani? This study takes place over a period of six months.

Utafiti huu utachukua miezi sita.

What are the risks? Je hatari ya kuhudhuria ni ipi?

The research will be conducted within structured interviews and confidentiality will be maintained.

Utafiti huu utachukua mfumo wa majadiliano ya mipangilio na usiri wa wahusika utazingatiwa.

What are the benefits? Manufaa ni yapi?
The benefit of this study is that it will identify ethical cogs in genomic data sharing in Genomic Wide Associated Studies in Africa. This will inform policies developed around ethical genomic data sharing to promote justice and dignity while promoting research efficiency.

Manufaa ya utafiti huu ni kugundua mazingitio ya maadili mema katika ugavi wa data kwa GWAS humu Afrika. Maarifa hii inaweza tumika kuweka mikakati ya ugavi wa data ya genomiks kwa njia ya uhaki na utu huku ikiboresha mienendo ya utafiti.

How will we protect your information and maintain confidentiality? Ni vipi ujumbe wako utahifadhiwa kwa usiri?
The information offered will be protected against sharing by technological methods and professional ethical policies.

What will happen with the findings? Matokeo yatafanyiwa nini?
The findings will be assessed to reveal gaps that need bridging in data sharing ethics of GWAS studies.

Majibu ya utafiti huu yatatumika kueleza mipengo ya maadili inayoweza kuchangia ugavi wa data ili kuboresha utafiti wa GWAS.

Compensation/ Fidia
The research will compensate participants for time spent as an opportunity cost. The compensation will cover for travelling expenses for face to face interviews.

Utafiti huu utakua na fidia ya kuhudhuria. Fidia hii ita shugulikia wanaotoka mbali watakoa hudhuria ukaguzi wa ana kwa ana.

Who can I contact? Ni nani naweza wasiliana naye?
If you have any questions, you can ask anyone from our team now or later. If you have questions later, you may contact [James Waweru, +254726647910, munuhejames2@gmail.com]. If you have questions about your rights as a study subject, you may contact:

Ukiwa na maswali yoyote ungetaka kuelekeza kwa wanao endeleza mradi huu unaweza fikia [James Waweru, +254726647910, munuhejames2@gmail.com]. Ukiwa na maswali ya kutekeleza haki zako kama mshirika unaweza pigia:

The Secretary ESRC
Amref Health Africa in Kenya
Wilson Airport, Lang'ata Road
Office Tel: +254 20 6994000
Mobile No: 0795746777
Fax: +254 20 606340
P.O Box 30125-00100
Nairobi, Kenya

Do you have any questions at this time? Una maswali yeyote kwa sasa?

Part II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to participate in this study.

Print name of Subject	
Signature of Subject	
DD/MM/YYYY	

If visually impaired, physically impaired, mentally impaired or illiterate

I have witnessed the accurate reading of the Consent Form to the potential study subject, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Subject	
Thumb/Foot print of Subject	
Signature of Witness	
DD/MM/YYYY	

Statement by the researcher/person taking consent

I confirm that the study subject was given an opportunity to ask questions about the study, and all the questions asked by the study subject have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the study subject.

Print Name of researcher/person taking the consent	
Signature of researcher/person taking the consent	
DD/MM/YYYY	

REF: AMREF – ESRC P1367/2023 **March 14, 2023**

James Munuhe Waweru
African Population Research Center
P.O. Box 10787-00100
Nairobi, Kenya
Tel: +254726647910
Email: munuhejames2@gmail.com

Dear James Munuhe Waweru,

RESEARCH PROTOCOL: ETHICAL ISSUES IN GENOMICS DATA SHARING WITH COMMERCIAL ENTITIES: A CASE STUDY OF THE AWI-GEN COLLABORATIVE PROJECT

Thank you for submitting your protocol to the Amref Ethics and Scientific Review Committee (ESRC).

This is to inform you that the ESRC has reviewed and approved your protocol. Your application approval number is ESRC P1367/2023. The approval period is from March 14, 2023, to March 13, 2024, and is subject to compliance with the following requirements:

a) Only approved documents (including informed consents, study instruments, advertising materials, material transfer agreements, etc.) will be used.
b) All changes including (amendments, deviations, violations, etc.) are submitted for review and approval by Amref ESRC before implementation.
c) Death and life-threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the Amref ESRC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to Amref ESRC within 72 hours.
e) Clearance for export of biological specimen must be obtained from the relevant government authorities for each batch of shipment/export.
f) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
g) In case of late renewal, the Amref ESRC shall not be held responsible for any serious adverse events (SAEs) that may occur as a result of research activities that were carried out after the expiry of approval.
h) Submission of an executive summary report within 90 days upon completion of the study to the Amref ESRC.
i) All government regulations for prevention and control of the spread of COVID-19 including social distancing, provision of personal protective equipment for participants and research assistants should be adhered to during data collection. All research assistants should be monitored for COVID 19 symptoms and referred for testing in case they present with symptoms.