

Informed Consent and Community Engagement in Genomic Research

Thesis submitted in accordance with the requirements of the
University of Liverpool for the degree of Doctor in Philosophy

by

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COMMUNITY ENGAGEMENT AND INFORMED CONSENT PROCESS IN GENOMIC RESEARCH

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ABSTRACT

The introduction of genomic research to, and emergence of biobanks in, sub-Saharan African countries raise ethical issues that require urgent attention. Firstly, there are concerns about whether individuals and communities would agree to participate in this type of research especially considering how communitarianism may affect their decision-making process. Secondly, there are controversies over whether the informed consent process as it is applied to other biomedical researches would be appropriate for genomic research in sub-Saharan Africa. And thirdly, the components of engagement of culturally distinct communities in genomic research are not yet clarified. Although community engagement during the recruitment stage have been described, there is dearth of information on effective strategies beyond this stage and which model is the most appropriate for sub-Saharan African settings.

Therefore, my research explored the opinions of indigenous potential research participants on involvement in genomic research and to storage and export of their biospecimens, assessed the roles of community leadership in and perceptions of community engagement and informed consent processes in genomic research and biomedical researchers' views. To obtain data for my qualitative study which is based on a methodological design adapted from grounded theory, I interviewed thirty biomedical researchers recruited from a research institution situated within the selected community, four community leaders and two community health workers; and conducted fifteen focus group sessions comprising 50 potential research participants organized by age and sex, namely: 1) adult (>30 years) males, 2) adult females, 3) youth (18-30 years) males, and 4) youth females. A mixed age-group was conducted to probe different views between the age groups. The data were transcribed verbatim and analyzed iteratively using constant comparative method to develop themes with the aid of Atlas-ti.

The potential research participants would not agree to donation, storage or export of their samples unless they trusted the researchers to use their samples in an ethical manner, but the biomedical researchers felt that they would agree if the community leaders approved of the research. There was consensus between the adult research participants and the biomedical researchers on the appropriateness of blanket consent type for genomic research but the community leaders, health workers and the youths prefer either reconsenting or delegated consent. Married adult female participants would consult their husbands before agreeing to participate. All participants agreed on the gatekeeping role of the community leadership. The themes on community engagement reflected a strategic model of four stages, namely: community approach, community interphase, community integration, and post-research cordiality, as the crucial phases for ensuring effective community participation. There was discordance and clear division between the adults and youths regarding the decision to participate in genomic research based on commitment to communal values. Adults based their decision to participate on altruism and furthering the common good while youths based their decision on personal benefits and preferences and considered the views and welfare of family members and neighbours.

This discordance suggests a generational shift, so I conceptualized a model of relative solidarity, which is different from communal solidarity typical of African communitarianism, for genomic research participation. To foster relational ethics, protect prospective research participants and ensure the success of genomic research, I proposed a strategic model of flow dynamics between the researcher(s), the community leaders, and potential research participants for effective community engagement. These findings suggest the need for a closer look at strategies for implementation of community engagement and informed consent in genomic research in this region. I recommend further studies on this emerging area of medical research.

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DECLARATION

This thesis is the result of my own work. The material contained in the thesis has not been presented, nor is currently being presented, either wholly or in part for any other degree qualification.

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ABBREVIATIONS

| | |
|---------|---|
| APOe | apolipoprotein epsilon |
| BRCA | Breast Related Cancer Antigen |
| CAB | Community Advisory Board |
| CBPR | Community-based participatory research |
| CE | Community engagement |
| CER | Community-engaged research |
| CDC | Centre for Diseases Control |
| CHO | Community health officer |
| CIOMS | Council of International Organisation of Medical Sciences |
| DART | Development of anti-retroviral therapy in Africa |
| DNA | deoxyribonucleic acid |
| DoH | Declaration of Helsinki |
| EE | Empirical ethics |
| ELSI | Ethical, legal and social issues |
| FGD | Focus group discussion |
| GCP | Good Clinical Practice |
| GLP | Good Laboratory Practice |
| HREC | Health Research Ethics Committee |
| ICH | International Committee on Harmonisation |
| IRB | Institutional Review Board |
| MTA | Material Transfer Agreement |
| NAFDAC | National Agency for Food and Drug Administration |
| NCHRE | Nigerian Code of Health Research Ethics |
| NHS-HRA | National Health Service – Health Research Authority |
| NHS REC | National Health Service Research Ethics Committee |
| NIH | National Institute of Health |
| PSA | Prostate Specific Antigen |

| | |
|-----------|--|
| RECs | Research Ethics Committees |
| ROs | Research Organisations |
| SEE | Symbiotic Empirical Ethics |
| SOPs | Standard Operating Procedures |
| UKRIO-CPR | United Kingdom Research Integrity Office's Code of Practice for Research |
| WHO | World Health Organisation |

LIST OF PUBLICATIONS FROM THESIS

Published works

- a. Ogunrin O, Woolfall K, Gabbay M, Frith L. Relative solidarity: conceptualizing communal participation in genomic research among potential research participants in a developing sub-Saharan African setting. PLoS ONE 2018, 13(4): e0195171. <https://doi.org/10.1371/journal.pone.0195171>
- b. Ogunrin, O. A., Taiwo, F., & Frith, L. (2018). Genomic literacy and awareness of ethical guidance for genomic research in sub-Saharan Africa: how prepared are biomedical researchers? Journal of Empirical Ethics in Human Research Ethics. *Accepted for Publication*.

Manuscripts awaiting submission

- a. Ogunrin O, Gabbay M, Woolfall K, Frith L. Community engagement in genomic research: proposing a strategic model for effective participation of indigenous communities.
- b. Ogunrin, O., Woolfall, K., Gabbay, M., Frith, L. Consent preferences for genomic research among potential research participants and biomedical researchers – Qualitative study of a sub-Saharan African population.

CHAPTER 1

INTRODUCTION - Overview of Thesis

1.1 Introduction to Research Background

There is no doubt that in the past century biomedical research has made significant contributions to medical progress and health care services. Genomic research in particular has revolutionized scientific analysis, understanding and treatment of hitherto complex, polygenic inherited or familial disorders. However, the technological sophistication of genomic research raises peculiar ethical issues which are currently being discussed in bioethics circles (de Vries et al., 2014; Ramsay, de Vries, Soodyall, Norris, & Sankoh, 2014). For example, advances in genomic research have engendered controversies on whether the informed consent process as it is applied to other biomedical research is appropriate for genomic research. These controversies are particularly pertinent in resource poor countries vulnerable to exploitation due to wealth inequality; as well as weak capacity for ethical review and oversight of research {Boggio, Biller-Andorno, Elger, Mauron & Capron, 2005}. With particular focus on informed consent, the global expansion of genomic research combined with rapid evolution of scientific knowledge, and the public health need to translate genomic research findings, requires development of new, effective approaches to the informed consent process to keep pace with these developments. Therefore, the need emerged for an informed consent approach that addresses the regulatory constraints of designing and implementing genomic research, through an approach that simultaneously acknowledges the concerns of individuals and diverse communities invited to participate in genomic research projects. This need is more germane in multi-ethnic and culturally diverse societies like sub-Saharan African countries where cultural beliefs and traditional practices may influence the consenting process.

In a related vein, the strategies for community engagement in genomic research is yet to be clearly defined. Community engagement is especially important because the process and outcomes of genomic research extend beyond the normal bounds of researcher-participant encounters. They affect other stakeholders in the participating community such as families, elders, community authority, and so on. This is so because genomic research often requires bio-banking, which refers to collection of biological specimens from family members and/or individuals from same community, storage of such specimens in biobanks, export to other countries, and analysis by foreign investigators unknown to study participants.

Furthermore, to avoid ethical conflicts in the conduct of genomic research, it is important to explore and understand the perceptions and views of potential research participants of this type of research. It is also important to ensure that biomedical researchers appreciate the contexts of participating communities. In sub-Saharan African communities, the decision-making process is known to be strongly influenced by communalism. Individuals' choices are subsumed under community or group decisions and shaped by dialogue and interactions among all concerned parties within communities. This peculiarity makes it imperative to thoroughly understand potential research participants' decision-making processes (Tangwa, 2000). In other words, there is an urgent need to understand the dynamics of community engagement and identify which type of consenting process is appropriate and acceptable to potential participants of genomic research in sub-Saharan Africa. Unfortunately, there is a dearth of studies that address the controversies surrounding the informed consent process within the context of resource-poor countries like sub-Saharan African countries. What is more, the role of community engagement in genomic research remains poorly defined in sub-Saharan African countries. These gaps in existing literature underscore the need for a study that explores the perceptions of potential genomic research

participants in sub-Saharan African countries (Benatar & Singer, 2010; de Vries & Pepper, 2012).

There is also an imbalance within genomic research as it is presently conducted. It is currently undertaken as international collaborative projects wherein funding originates from agencies in high-income countries to support research programs and projects conducted by researchers from high-income countries, while study participants are from low and medium income countries (King, Kolopack, Merritt, & Lavery, 2014). Benefits that could be derived from working with externally sponsored researchers, which include capacity development and significant improvements to health outcomes and investment, have been limited by imbalances in ethical regulations of trials and administrative burdens (Lang & Siribaddana, 2012). Therefore, the need to prevent unethical genomic trials in developing countries has generated considerable interests among bioethicists. In this regard, there is an emerging concern about bio-banking as well as increased number of clinical trials and research programs without a corresponding development of an ethical framework for such studies in resource-poor settings (Mystakidou, Panagiotou, Katsaragakis, Tsilika, & Parpa, 2009; Ramsay, de Vries, Soodyall, Norris, & Sankoh, 2014; P Tindana, Molyneux, Bull, & Parker, 2014).

For example, in Nigeria - a sub-Saharan African country, there is a national code of health research ethics. The Code represents the collective concern of the government and people of Nigeria to ensure the protection of human participants in scientific research. This code applies to all health research involving human participants, conducted, supported or otherwise subject to regulation by any institution in Nigeria (Nigerian Code for Health Research Ethics, 2007). Despite its laudable goals, the Code does not specifically address issues relating to genetic or

genomic research except for the material transfer agreement (MTA)¹ which is applicable to storage and transfer of bio-specimens.

The level of development of ethical guidelines for genomic research in some sub-Saharan African countries is like that in Nigeria. Therefore, as genomic research gains impetus in sub-Saharan Africa, including Nigeria, this study will aid the articulation of an ethical framework that will guide the conduct of scientifically valid and ethically acceptable genomic projects or trials.

1.2 Overview of study

To fill the above-mentioned gaps, I designed and conducted a qualitative study with the goal of defining the dynamics and scope of community participation and engagement, and how the interplay of culture and communitarianism² affect the process of informed consent, for genomic research in Nigeria. My specific research objectives are:

- a) to explore the perception and interpretation of genomic research among indigenous Nigerian population;
- b) to evaluate the role of communitarianism in decision making in the context of genomic research;
- c) to assess the roles of community elders, opinion leaders, family heads and community members in the process of considering participation in genomic research and more specifically in bio-banking;

¹ The material transfer agreement is a documentation of details of storage (duration, manner, responsible contact) and export of biological samples outside the country in the research protocol, and such MTA must be approved by the institutional ethics committee (Nigerian National Code of Health Research Ethics).

² Communitarianism, according to Callahan (2003), is an ethical concept that assumes that human beings are social animals, not isolated individuals, whose lives are lived out within deeply penetrating social, political and cultural institutions and practices.

d) to explore how biomedical researchers perceive and understand community engagement and informed consent process in genomic research as well as banking of bio-specimens and;

e) to propose guidelines for ethical conduct of genomic research in Nigeria that will be incorporated into the National Code of Health Research Ethics.

My thesis is divided into four main parts, and in part one, I introduce my research background in chapter one. Chapter two outlines the key concepts in genomic research. Also, I emphasize uses and governance of biobanks, and the situation of biobanks in sub-Saharan Africa. In chapter three, I discuss key ethical issues of informed consent and community engagement, including health-related decision-making processes in sub-Saharan Africa. These issues constitute the focus of my thesis. In chapter four, I examine ethical theories and principles underpinning ethical discourse in biomedical research that are applicable to my project. In chapter five, I review the literature on bioethics in sub-Saharan Africa including regional ethical guidelines; compare UK and European ethical guidelines with the Nigerian National Code of Health Research Ethics. Finally, in chapter six I discuss empirical research in bioethics with emphasis on the empirical shift and strategies for integrating data and theory to make normative conclusions, an approach I use to answer my research questions.

In part two, I discuss my methodological design based on a form of grounded theory, the details of my field work, how I ensure the quality of my data and use constant comparative method for analysis. Part three focuses on my data analysis and results. I present the demographics of my study participants and an overview of my thematic analysis in chapter eight. I discuss decision-making in bio-banking emphasising the facilitators and barriers to participation in genomic research from my data in chapter nine; consent process in genomic research including

types of consent preferred by potential research participants and biomedical researchers in chapter ten; and in chapter eleven community connections, communitarianism and proposed model for community engagement in genomic research. I also discuss the discordant views in my data explaining the divergent opinions among the potential research participants on one hand, and between the potential research participants and biomedical researchers on the other hand. I integrate my data with existing ethical theories; draw normative conclusions; and ultimately build theories from my analysis using the symbiotic empirical ethics approach.

In the concluding part, I give a synopsis of the discussion of my findings, reflect on the outcome of my research, and discuss the ethical/policy, educational, research and social implications of my findings. In addition, I make recommendations on how to effectively engage a participating community and prospective research participants in genomic research. I propose models for incorporating the views of the research participants and biomedical researchers into ethical guidelines for conduct of bio-banking research in Nigeria and other sub-Saharan African countries. The proposed guideline aims to minimize ethical conflicts, thus promoting successful implementation of genomic research in the region.

PART 1

THEORETICAL CONSIDERATIONS

and

REVIEW OF LITERATURE

CHAPTER 2

Definitions of Key Concepts and Ethical Issues in Genomic Research

2.1 Introduction

In this second chapter, I examine the key concepts that are germane to my research topic. These concepts include genomic and genetic research vis-à-vis definition, uses, governance and ethical implications of bio-banking. Thereafter, I discuss in greater details the concepts of informed consent; community engagement; and supplementary ethical issues such as feedback of results of genomic testing.

2.2 Genomic and Genetic research

Genomics and genetics may appear similar, and are often used interchangeably, because both deal with the study of genes. However, the two concepts differ in minor but significant ways. Genomics can be considered a sub-specialty within genetics; and it involves the study of the whole genome. The genome is the complete set of deoxyribonucleic acid (DNA) within a single cell of an organism. In genomics, recombinant DNA methods and bioinformatics are used to sequence, assemble, and analyze the function and structure of genomes (Kreiner & Irion, 2013; Platt, Bollinger, Dvoskin, Kardia, & Kaufman, 2014; U.S. Department of Health and Human Services, 2017).

In other words, genomic research is concerned with studying larger parts of the human genome or the entire genome. Genomic research may involve either sequencing the whole, or part of the genome, to find all positions that vary between individuals or seeking positions that frequently vary between individuals within a class of variants called single nucleotide polymorphisms (SNPs). The genomic profile of individuals may then be combined with clinical data to provide novel insights into gene sequences associated with susceptibility or resistance to a

disease. This often involves comparing variations between populations to identify the range of genetic variants in diseases. This scientific innovation has resulted in advances that triggered a revolution in discovery-based research as a strategy for understanding complex human biological systems like the nervous system (Baum, 2016; H3 Africa Working Group, 2011; Kreiner & Irion, 2013).

Genomic research has been found useful in studying hereditary patterns (such as malaria resistance or susceptibility to developing diabetes); elucidating genetic differences between people and populations (like tracking migration patterns); as well as variations in drug metabolism (pharmacogenomics). Oftentimes, families are used in genomic studies - for example in linkage analysis wherein multiple generations are followed up to identify patterns in particular disease. At other times, mother-father-child trios are used in investigating the transmission of genetic traits to children (Global Health Reviewers, 2013).

Genetics, on the other hand, is the study of genes and their roles in inheritance. Genetic research focuses on analysis of a specific gene or cluster of genes which has been identified as being related to a specific condition. Genetic research investigates the roles and functions of single genes and differs from genomics unless the aim of the research is to explore any of these three scenarios: effect of genes on, or place of genes in, or response of genes to the entire genomes' networks.

2.2.1 The Human Genome and Ethics: Historical perspective

Historically, the Human Genome Project, completed in 2003, sequenced the entire genome for one specific person. However, it was not until 2007 that the sequence was declared completed, when all chromosomes in the genome were assembled (Harris, Parrott, & Dorgan, 2004; National Institutes of Health, 2010). The Human Genome Project paved the way for a

steady rise in the number of international collaborative genomic research projects; and gave birth to networks of scientists collaborating across high-, and low-income (resource poor) countries (Jantina de Vries et al., 2015; National Institutes of Health, 2010). In the years since then, under the auspices of the 1000 Genomes Project, significant advances were made in sequencing the genomes of many individuals. Using more efficient sequencing technologies and significant bioinformatics resources from a large international collaboration, the 1000 Genome Project announced the sequencing of 1,092 genomes in October 2012 (Abecasis et al., 2013).

However, analysis of human genomic data engenders profound ethical, legal, and social implications for human societies. The 57th World Health Assembly in 2004 noted that, *‘having considered the report on genomics and world health, WHO wishes to promote the benefits of the genomics revolution for the health of populations in developed and developing countries alike’*, but also *‘is aware that genomics raises concerns about safety and, has new ethical, legal, social and economic implications’* (WHO, 2004; p.21). These concerns as acknowledged by the WHO, prompted inquiries into how to ethically undertake genomic research; while minimizing risks and exploitation; and maximizing the benefits of this ground-breaking innovation. Consequently, the past two decades have witnessed efforts to address the ethical, legal, and social issues (ELSI) in genomic research. A good example is the attempt to articulate an informed consent process that is appropriate for bio-banking and secondary uses of human biological specimens which is part of my research focus.

Analyses of human biological specimens such as blood, saliva, urine, and organs are an important component of genomic research. This sometimes requires use of biobanks in the collection, storage and export of such samples; and collation of relevant clinical data from consenting donors thus making the informed consent process complicated, especially in

developing countries of sub-Saharan Africa where evolving literature suggests serious ambiguity and complex scenarios. This ambiguity is possibly due to the application of traditional approaches of informed consent in genomic research, coupled with few or no ethical guidelines for the implementation of genomic research. For a clearer understanding of this complexity, I discuss biobanks in subsequent sections, to highlight their role in genomic research and the ethical issues associated with storage and export of human biological specimens.

2.3 Bio-banking

There has been remarkable investment into setting up and managing biobanks in many countries following the success of the Human Genome Project in 2001³. As an offshoot of that feat, there was extensive application of genetic and genomics analysis in the diagnosis of non-communicable, polygenic disorders with the possibility of development of treatment modalities, and its application to pharmacogenomics research. However, bio-banking research involves multiple players with different interests and expertise, including donors; relatives of donors, bio-bankers (scientists who collect, store and manage samples and information); end users of bio-specimens (privately or publicly funded researchers); and possibly clinicians who must interpret findings. Consequently, bio-banking raises important but complex ethical issues in health policy and research. These issues revolve around storage and analysis of bio-specimens, and the usage of data on donors' health, lifestyle or genealogy.

For example, there is the issue of an appropriate informed consent approach which permits donors to give consent in a voluntary manner after full disclosure of the purposes, nature, significance and implications of the collection and use of their bio-specimens. Such an approach

³ The human genome project is discussed in the preceding paragraphs, under Historical perspective, sub-section 2.2.1, p.9

must recognize that genomic research may involve more than the individual and therefore, permit privacy as well as confidentiality in handling and transferring donors' information. These ethical issues affect all bio-bank stakeholders including donors and researchers alike. However, most studies on bio-banks have focused on the public and donors' perceptions of ethical issues relating to bio-banks. Few have focused on the views of scientists or researchers who manage the bio-banks or use the bio-specimens. In succeeding sections, I appraise discrepancies in bio-bank definitions, discuss uses and regulation of bio-banks, and review the status of bio-banks in sub-Saharan Africa.

2.3.1 Discrepancies in bio-bank definitions

The definition of bio-banks varies from one set of national or international guidelines to the other. Unfortunately, these discrepancies in definitions hamper effective governance and management of biobanks. Some definitions emphasize the use of bio-specimens while others focus on scope of materials which are banked. Most definitions however agreed on two common criteria; the use of biobanks as repositories of biological specimens and donors' data, and its use for research purposes. For example, the Swiss Academy of Medical Sciences stated that biobanks are systematic collections of samples of human body substances and DNA as carrier of genetic information. Data that contain personal information on the donor are stored, either together with the samples or separately (Swiss Academy of Medical Sciences., 2006). The UK Biobank Ethics and Governance Council defined biobanks as 'rich collections of data plus bio-specimens, specifically developed as resources for research' (UK Biobank Ethics and Governance Council, 2007). Earlier, the Wellcome Trust and UK Medical Research Council defined bio-banks as service units, non-profit organisations set up for the collection and preservation of biological materials used for research and studies on biodiversity (The Wellcome Trust & Medical Research

Council, 2001). Broader definitions are used by the Organisation for Economic Co-operation and Development (OECD), Expert Group of the European Commission and Swedish Bio-Banks Health Act of 2002 as they address scope of bio-specimens and diversity of uses to include research, treatment and diagnosis (OECD, 2009; Borovečki, Caenazzo, Ježek, Karija-Vlahović, & Golubić, 2014; Ministry of Health and Social Affairs, 2002). The National Health and Medical Council of Australia and German National Ethics Council also emphasise scope and use (Australian Government National Health and Medical Research Council, 2010; German National Ethics Council, 2004). For the process of harmonization, Fransson *et al* opined that the biobank community needs to support and use a common terminology (Fransson, Rial-Sebbag, Brochhausen, & Litton, 2014).

I observed that these definitions differed in their details though most agree on the broad aspects of being repositories of biological samples with accompanying data. Similar observation was made by Shaw and colleagues when they revealed a substantial disagreement among bio-bankers on what exactly constitutes a biobank, although there was general consensus regarding the key criteria of biological samples, data and the use for research but their views were divergent on the importance of size, sharing and diversity of sample (Shaw, Elger, & Colledge, 2014). This is problematic because using different terminology or definition for various biobanks allows different regulatory regimes and consent procedures to be applied. Also, the laws and regulations designed to govern biobanks are unlikely to be effective if bio-bankers are unaware that their collections of samples are biobanks, or if they are reluctant to define them as such due to the regulatory requirements which can ensue. More importantly, it will limit collaboration among researchers because it will negatively impact on the networking of biobanks resulting in reduced awareness of their existence and value of their sample collections.

2.3.2 Uses and regulation of biobanks

Human bodily substances of all kinds have been collected, stored and used for various purposes since the beginnings of scientific medicine, and a need for specific regulation in this field has never been felt (Chalmers, 2011). But with the emergence of dedicated genetic bio-banks which are set up specifically to examine DNA and establish how mutations cause diseases, and thus develop treatments to counter them, this exceptional nature of genetic information in comparison with other kinds of medical information brought about the imperativeness for public trust and concerns for group harms such as discrimination and stigmatization. Human tissue samples are essential tools for genomic research and translating biomedical research into real improvements in health care such as in pharmacogenomics research and for the analysis that aims to identify potential biomarkers or drug targets by any of the new generation genomic tests utilizing DNA marker, RNA expression level, or protein activity.

Though biobanks could lead to these significant breakthroughs in medical and pharmaceutical research, they also arouse genuine ethical, legal and social concerns. The main ethical concerns include donor protection because of uncontrolled use of samples and data, and the fact that potential donors might be pressurized into assuming unreasonable risks or imprudently divulging personal information. Hence, there has been increasing attention to identifying solutions to the ethical, legal and social challenges posed by biobanks on a level of governance. A case for a top-down superstructure of detailed rules and guidelines to be imposed on biobank researchers was suggested to ensure strict governance (Chalmers, 2011). Meanwhile some authors have argued that the Institutional Review Boards or Research Ethics Committees (IRBs/RECs) and data protection authorities have managed quite well to keep up with new initiatives in genomic research enterprise to balance the different interests at stake. That is, the existing ethical review boards are

playing a central role guided by ethical guidelines like the Helsinki Declaration, offering solutions in resolution of ethical dilemmas. Furthermore, it has been proposed that self-regulation by researchers and lessons deduced from literature which have addressed bio-banking governance in association with different research initiatives and protocols may be sufficient in establishing governance strategies for bio-banking (Douglas, van El, Faulkner, & Cornel, 2012; O'Doherty et al., 2011; Whitley, Kanellopoulou, & Kaye, 2012).

Secko *et al* proposed four principles to guide the implementation of bio-banking governance structures, namely; recognition of participants and publics as a collective body, trustworthiness, adaptivity and fit between the nature of a biobank and the specific structural governance elements. These principles overlap and work in concert to produce 'adaptive governance'. This model has been criticized as not encompassing because it did not cover the issues of intellectual property and community specific needs (Secko, Preto, Niemeyer, & Burgess, 2009).

The International Declaration on Human Genetic Data by UNESCO in 2004 was the first international legal document that prescribed several rules about biological samples and on the personal data which may be collected from those samples. This document aims at ensuring the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human proteomic data and of the biological samples in keeping with the requirements of equality, justice and solidarity (UNESCO, 2004). Since then there have been several national and international guidelines and recommendations but these guidelines fail to address in sufficient detail, or do not agree on, a number of important issues raised by bio-banking activities although consensus exists on few issues and solutions (Boggio, Biller-Andorno, Elger, Mauron, & Capron, 2005). This calls for much empirical and theoretical work on ethics of

bio-banking and genomic research to highlight these ethical dilemmas and disagreements in guidelines with the objective of identifying possible resolutions.

In the United States, there are guidelines that regulate research which are applicable to bio-banking governance. For example, in 1996, the Health Insurance Portability Accountability Act (HIPPA) was passed by the US Congress, administered by the US Department of Health and Human Services, and it is intended to protect patients' medical records. In addition, there is the Common rule (45 Code of Federal Regulations) which guaranteed ethical treatment to Americans when they agree to participate in biomedical research including genetic and genomic research (Office for Human Research Protections & U.S. Department of Health and Human Services, 2009; Office of the Secretary, 2002). In 2008, the Genetic Information Non-discrimination Act (GINA) was signed into law. The law is intended to protect individuals from the potential negatives that can come about through genetic research and its outcomes.

With the completion of the Human Genome project, and the ability to test our individual genetic code or DNA, more tests are being developed every day to help individuals learn what medical problems they may inherit from their ancestors. Bio-researchers can assist individuals in knowing what their genetic makeups are, so they can then work to prevent the diseases their genes may develop. Consequently, individuals can choose from several medical preventive options such as frequent or periodic mammograms; or mastectomy among others. Unfortunately, this advancement can spawn unintended consequences. Health insurers and employers could use the information against people. These legal and ethical guidelines protect individuals from such discrimination (Annas, Roche, & Green, 2008).

2.3.3 Examples of bio-banks

There are several examples of population-based biobanks, namely:

- a. POPGEN – Schleswig-Holstein hosted by the Kiel University Hospital began in 2002. The aim of the project is to link disease-relevant genotypes to patients held to be fairly representative of the population (Hobbs, Starkbaum, Gottweis, Wichmann, & Gottweis, 2012).
- b. UK Bio-Bank Project is a comprehensive study of the health effects of environmental factors, lifestyle and heredity. Besides the identification of risk factors for specific disorders, scientists hope to obtain a better understanding of the heterogeneity observed within individual groups of diseases and to identify biomarkers in human blood (Sak, Pawlikowski, Goniewicz, & Witt, 2012; UK Biobank Ethics and Governance Council, 2007).
- c. Estonia Genome Project is a database being used in research to identify correlation between genetic factors and common diseases among the Estonian population (Sak et al., 2012).
- d. Icelandic Health Sector Database has attracted most public attention. It contained the health data for the entire population of Iceland. The medical records have been kept since 1915 and contained individual medical histories of all patients treated (Haga & Beskow, 2008).

There were biobanks which are also large population-based like the afore-mentioned ones but were used in the past decades for epidemiological studies. An outstanding example is the Framingham Heart Study⁴ which was one of the most important studies in the field of medical epidemiology. It was designed for long-term investigations of factors contributing to

⁴ Framingham Heart Study started in late 1940s and participants were examined continuously for a period of about 40 years. The data obtained included changing lifestyles of men and women who were healthy at the beginning of the study which were correlated with stature and weight and the occurrence of diseases. It also included measurement of blood sugar levels, hypertension and cholesterol values to test for correlations with the incidence of strokes, angina pectoris, heart attacks and cardiac infarctions

cardiovascular diseases in almost the entire population of the small town of Framingham, Massachusetts, USA (Mahmooda, Levy, Vasan, & Wang, 2014).

The MONICA⁵ (Monitoring of Cardiovascular Diseases), KORA⁶ (Cooperative Health Research in the Augsburg Region) and PROCAM⁷ (Prospective Cardiovascular Munster) are other examples (Assman & Schulte, 1988; Hobbs et al., 2012).

In 2010, the National Institute of Health and Wellcome Trust announced a partnership named Human Hereditary and Health in Africa (H3Africa)⁸ to use genomic and clinical tools to identify the genetic and environmental contributions to communicable and non-communicable diseases in Africa. This project involves the setting up of regional and national biobanks to address common ethical issues, data ownership and data sharing. The biobanks, once established, will offer the opportunity to assess population prevalence of specific genes and variants, simplify the search for molecular markers, improve targeted drug discovery and development for disease management, refine strategies for disease prevention, and provide the data necessary for evidence-based

⁵ The MONICA project comprised three consecutive representative cross-sectional studies initiated by the WHO and conducted since 1984 in 25 countries in Europe, Australia and North America with standardized protocols. It was the first multi-national scale attempt to correlate the incidence of these diseases with known risk factors comprising personal life style, quality of health care system and economic conditions.

⁶ KORA was the follow-up project of MONICA and was conducted under the auspices of the German Science Foundation Research Centre for Environment and Health. The database was started in Augsburg and the surrounding regions in 1985 to investigate the risk factors for cardiovascular diseases, diabetes mellitus and allergies. Medical information on the subjects was recorded, and blood samples and in some case cases tissue samples and cells were stored.

⁷ Prospective Cardiovascular Munster (PROCAM) is thought to be the largest population-based national cohort study of the causes of cardiac infarction in Europe. It was hosted by the Arteriosclerosis Research Department of the University of Munster. The database comprised information from 30,000 employees of major industrial and commercial enterprises and public authorities in Westphalia and the northern Ruhr area between 1978 and 1985. The results of this study led to the establishment of computer-based personal risk profiles whereby physicians can calculate the risk of infarction in their patients based on blood pressure, cholesterol levels, smoking habits and other risk factors.

⁸ The H3Africa Initiative has as one of its goals the establishment of necessary research infrastructure to facilitate contemporary research approach to the study of genomics, and this has resulted in the establishment of biobanks in some African countries.

decision-making. The last five years witnessed the emergence of biobanks in the sub-Saharan African countries mainly due to the H3Africa Initiative. Therefore, I briefly discuss the state of biobanks in sub-Saharan Africa.

2.3.4 Biobanks in sub-Saharan Africa

A major strategy to unravelling the etiologies and the molecular genetic factors relevant in African diseases, including both infections and complex degenerative diseases as well as cancer, is the banking of well annotated and preserved bio-specimens acquired from native African ethnic groups. These bio-specimens will need to be compared with non-African populations and/or with African Americans to identify underlying determinants responsible for genetic predisposition. From my viewpoint, this implies sharing and transfer of bio-specimens within and outside the continent. Though a noble enterprise, it requires organized biobank infrastructural support in form of clinical centers with dedicated resources for storage and processing of bio-specimens and robust ethical institutional capability.

In Africa, the H3 Africa initiative has initiated biobanks that will collect DNA and medical information from hundreds of thousands of African people facilitating genetic epidemiology studies to uncover gene-environmental interactions by linking genetic variations to environmental factors. The ultimate goal is to accelerate the discovery of vaccines, drugs and diagnostics (Gasmelseed, Elsir, DeBlasio, & Biunno, 2012). Interestingly, the H3 Africa initiative was not the first to establish biobanks in Africa. The Gambia was the first African country to establish a national DNA bank. The Africa Centre in South Africa has also built up an extensive collection of bio-specimens over the past decade. However these biobanks might have emerged without formal legal or ethical oversight (Sirugo et al., 2004). Additionally, many institutions have storage of bio-samples especially pathological human specimens for research purposes but

they may not be formal biobanks. There are clinical databases in Nigeria that store human data and some genetic information but do not store human bio-specimens so therefore do not qualify to be called bio-banks. Examples of these clinical databases include the cancer registries in some tertiary teaching hospitals.

While it is unlikely that there will be an agreement on the establishment of one central biobank in Africa, efforts should be made to ensure there is uniformity of governance of biobanks throughout Africa to ensure easy transfer of bio-specimens throughout the continent and ultimately encourage collaboration. A recent study by Staunton and Moodley showed that biobanking guidelines, which are available in few countries, differ substantially across sub-Saharan Africa and are often conflicted across borders. They opined that this can potentially negatively impact collaboration, and observed that the existing ethical guidelines do not recognize the ethical dilemmas arising from transfer of bio-specimens and are unsuitable to regulate biobanks (Staunton & Moodley, 2013). In addition, the guidelines addressed few ethical concerns therefore making them sketchy and incomplete. The existing guidelines are illustrated in Table 1.

Few studies from Africa have examined the informed consent process in biobanking when compared with developed countries. Staunton and Moodley identified six publications, namely: a study on ethical issues encountered by Ethics Research Committees in Kenya; a Nigerian study on participants' views on storage and re-use of bio-specimens; two South African studies on participants' views on storage and re-use of biological samples; another study on seeking consent for genetic research in Ghana; and a study of Ugandan donors' views on stored biological samples (Staunton & Moodley, 2013). These small-scale studies explored the views of African participants on consent and re-use of their samples in biobank research and showed that most of

the citizens were favorably disposed to reuse of their samples but with conditions attached. For example, sample reuse should be based on future institutional review board or the Federal Ministry of Health's review of the research protocols. Contrariwise, a South African study showed that participants would not want REC to consent on their behalf (Abayomi et al., 2013).

Furthermore, Staunton and Moodley observed that there is a paucity of studies on the opinions of research participants in Africa on the ethical issues raised by biobanking unlike international counterparts (Staunton & Moodley, 2013), and this underscores the need for such research, a gap my project sought to fill. At present, biological sample and data transfer within and out of Africa is shrouded in controversy due to lack of ethical guidelines and governance structure. The emerging trends with the H3Africa project and the establishment of biobanks in Africa necessitates definition of ethical and legal governance structures that will oversee the operations of these biobanks. This is necessary to protect donors, respect cultural perspectives and ensure ready availability of ethically sourced bio-specimens.

To foster collaboration and ensure standardisation of guidelines and procedures in genomic research, the UK Human Tissue Authority's Code of Practice recommends that the bio-samples' importer put in place SOPs which clearly set out how informed consent was obtained and how the information will be treated as confidential. Furthermore, the material must be sourced in accordance with the ethical and legal review standards of England, Wales and Northern Ireland. Similarly, harmonization of guidelines is needed in sub-Saharan Africa (SSA) to foster collaboration and ensure success of the biobanking projects, and the guidelines should reflect the unique ethical issues arising out of storage and secondary uses of bio-specimens. Research into the view of potential research participants is paramount as this can aid in the drafting of any new harmonization guidelines. This is one of the major reasons I chose to explore

the opinions of potential research participants on what influenced their decision to participate in genomic research and which type of consent process would they prefer, with the expectation that the findings of my project will serve as a template for formulation of ethical guidelines for conduct of genomic research in sub-Saharan African countries.

Also, the issues confronting RECs and researchers in Africa include what consent approaches are appropriate for collecting, storing, and using research participants' bio-specimens and their associated data, whether and how language in original consent forms should be considered when conducting secondary studies using stored bio-specimens, what level of risk (no more than minimal or greater than minimal) should be assigned to studies using stored bio-specimens, and what requirements should be imposed for sharing bio-specimens with internal and external researchers (Edwards, Cadigan, Evans, & Henderson, 2013; Meslin & Quaid, 2004; Olson et al., 2014). In order to meet the unique requirements of performing next generation sequencing-related research in African populations, it was suggested that novel approaches to the informed consent process are required (Wright, Koornhof, Adeyemo, & Tiffin, 2013).

Table 1 Sub-Saharan African Ethical Guidelines on bio-banking of samples⁹

| Country | Guideline | Topics covered |
|--------------|--|---|
| South Africa | National Health Act 2003 Department of Health, Ethics in Health Research: Principle, Structures and Processes | Informed consent, re-contact, re-consent Secondary use of samples, informed consent, re-contact, re-consent, waiving of consent, confidentiality |
| Nigeria | National Code of Health Research Ethics 2007 | Export and import of samples, MTAs |
| Kenya | National Council for Science and Technology Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya 2004 | Informed consent, re-contact, re-consent |
| Botswana | Ministry of Health Standard Operating Procedures for Review of Biomedical and Bio-behavioural research in Botswana | Informed consent, export/import of samples/MTAs |
| The Gambia | Guidelines of the National DNA bank 2001 | Confidentiality, coding, anonymisation, informed consent, re-contact, re-consent |
| Uganda | Uganda National Council for Science and Technology National Guidelines for Research involving humans as research participants 2005 | Export/import of samples/MTAs |
| Zambia | The National Research Act 2013 | Informed consent, export/import of samples/MTAs |
| Ethiopia | Ethiopian Science and Technology Commission National Health Science and Technology Council, National Research Ethics Guidelines 2005 | Export/import of samples/MTAs |
| Malawi | National Health sciences Research Committee, Policy Requirements, Procedures and Guidelines for the conduct and review of human genetic research in Malawi | Export/import of samples/MTAs |
| Tanzania | Human DNA Regulation Act 2009 | Informed consent |
| Sudan | National Guidelines for Ethical Conduct of Research involving human subjects 2008 | Informed consent, confidentiality, privacy, secondary use of samples |

⁹ *adapted from Staunton and Moodley (2013)*

2.4 Conclusion

In conclusion, though the H3Africa project among other benefits aims to build research capacity within Africa, many jurisdictions within Africa currently do not have national legislation or guidelines on the use of stored biological samples. This is further complicated by lack of research on the appropriate consent process and perceptions of African people on the use of their stored biological data. Therefore, to ensure good governance of biobanks, I attempt to fill these gaps vis-à-vis exploring the opinions of potential research participants and biomedical researchers on appropriate consent procedures acceptable for genomic research, and views on storage and export of bio-specimens. In the next chapter, I present the key ethical issues encountered in genomic research which I address in my thesis.

CHAPTER 3

Key Ethical Issues in Genomic Research

3.1 Introduction

The key ethical issues encountered in genomic research include appropriate informed consent, effective community engagement, feedback of results, confidentiality, and bio-banking of specimens. These issues constitute major challenges in conduct of genomic research in sub-Saharan Africa. First because there is dearth of information on how these ethical issues manifest in sub-Saharan African communities and second, because of lack of guidelines for bio-banking research. In this section, I discuss these ethical issues, highlighting the peculiarities of informed consent and strategies of engaging communities in developed and developing countries.

3.2 Informed Consent

3.2.1 Decision making and informed consent in health research

The decision to participate in research should be autonomous and voluntary. This is the basis for informed consent in research involving human participants but the consent process has continued to pose challenges in all settings (Dawson & Kass, 2005). The concept of respect of person or autonomy constitutes the first ‘commandment’ in the Nuremberg Code and the Belmont Report, both guidelines came about as a result of the atrocities committed by scientists during the Second World War and in United States Tuskegee’s syphilis trial¹⁰ respectively (Ghooi, 2011; United States. National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research., 1978)).

¹⁰ Tuskegee trial was conducted in United States to study the natural course of syphilitic infection among adult male black African Americans without obtaining valid informed consent and they were denied treatment with Penicillin when this treatment became available.

Decision-making process is however complex as it is influenced by many factors like culture, religion, societal norms, literacy and personal identity. Likewise, the informed consent process, since it is hinged on informed choice of the individual, may be influenced by these factors. For example, the cultural norms and practices may influence decision of members of a community to participate in research. Mystakidou et al (2009), in a systematic review, demonstrated that cultural barriers due to communitarianism, illiteracy, language barriers or lack of true understanding of the entire study, and diminished autonomy were some of the ethical and practical challenges in implementing informed consent in HIV/AIDS clinical trials in resource limited countries in 44 studies (Mystakidou et al., 2009). In developing African countries for example where community elders' approval for conduct of research in a community is considered 'community consent' because of respect for traditional authority, and individuals are not given opportunity to express their autonomous choices, the process does not conform to informed consent as it is known in conventional research scenarios. Illiteracy and language barriers adversely affect comprehension of consent documents, understanding of what the research is about, the possible risks and benefits, thus making the decision less informed.

The goal of obtaining informed consent is to enhance and maintain the right of research participants to freely participate and have the right not to participate. Some authors have observed the disparity in this process in international collaborative research involving developed and developing countries whereby getting informed consent in developing countries is incompatible with the socio-cultural setting of the study participants (Dawson & Kass, 2005; Izadi, Fazel, Nasiri-Vanashi, Saadat, & Taheri, 2012). For example in the setting of genomic research, adhering to cultural beliefs and practices regarding donating any body part, including blood, in sub-Saharan Africa poses challenges to informed consent and research participation, and may

require different approaches (H3Africa Consortium, 2014; Wright et al., 2013). This becomes more obvious in resource poor settings where lack of ethical regulatory bodies results in weak capacity for ethical review and oversight of research, and since research sites are situated in these resource limited countries, ethical guidelines stipulate that independent ethical review by a local ethics committee is mandatory (Nuffield Council on Bioethics, 2002; UK Research Integrity Office, 2009; World Medical Association, 2008). The informed consent process used in developed countries are often adopted in resource poor countries thus constituting ‘ethical imperialism’¹¹ (Macklin, 1999).

The lack of ethical regulation of research in the developing countries paves way for adoption and application of ethical guidelines from developed countries, and such guidelines may reflect moral values and standards different from those of the developing countries. The application of ethical guidelines from developed countries in culturally different developing countries may be justified by the concept of ‘ethical universalism’¹². This approach however raises a debate between ethical universalism and ‘ethical relativism’¹³. The concept of ethical or moral universalism is anchored on two lines of argument, first that morality by definition is universal therefore if a rule is not universal then it is not a moral value; and second that morality is universal because this is how lay people think of the concept of morality (Alvarez, 2001;

¹¹ Ethical imperialism is a concept that ethical standards which exist in one’s home country are applied to activities in other countries or on the internet. For example, applying ethical guidelines of a developed country to research projects conducted in developing countries with different culturally distinct population and norms.

¹² Ethical universalism is a concept that assumes that morality is universal hence same moral rules should apply to everyone irrespective of who or where you are. Analytic philosophers have argued that moral values are indeed universal but not absolute thus allowing for application across cultures.

¹³ Ethical relativism is the theory that morality is relative to the norms of one’s culture, that is, whether our action is right or wrong depends on the moral norms of the society in which it is practiced. It is believed this theory is a more realistic perspective on why different cultures can view the same actions differently. It is based on the ethos that acts are morally right for some people in some contexts and morally wrong for other people or in other contexts.

Mbugua, 2011; Fayemi & Macaulay-Adeyelu, 2016). These arguments have been criticized as assumptions because they revolve around circular reasoning (Kim Lutzen, 1997). This jeopardizes validity of research in the developing countries because if research is implemented in these developing countries based on ethics review and approval from an ethics committee in a developed country using its guideline, then the standard of review is unlikely to consider socio-cultural issues of the developing country where the participants are domiciled. To maintain the autonomy of the potential research participants in international collaborative research involving developed and developing countries, and prevent potential ethical issues that may arise from non-consideration of cultural sensitivity and community health priorities, the adoption of ethical relativism may be considered. This however should not be construed to imply that moral relativism is superior to moral universalism as the former has its own flaws, the discussion of which is beyond the scope of my thesis¹⁴. In line with my research objectives, identifying appropriate informed consent process and community engagement strategies applicable to, and factors that make potential research participants agree to participate in, genomic research will allow for development of specific ethical guidelines based on these factors, thus acceptable for implementation of this type of research in culturally diverse settings. Therefore, to prevent potential ethical conflicts in genomic research, it is important to evaluate the peculiarities of the decision-making process in developing countries and adopt a paradigm of an effective consent process that is both acceptable and feasible. Next, I define decision-making and informed consent processes, discuss the concept of informed consent and critique the epistemology that underpins consent in developed and developing countries.

¹⁴ The debate on ethical/moral universalism and ethical relativism is discussed in details by Fayemi & Macaulay-Adeyelu (2016) in their paper on 'Decolonizing Bioethics in Africa', and Mbugua (2011) in his paper on 'Respect for cultural diversity and the empirical turns in bioethics: a call for caution'.

3.2.1.1 Decision making

Decision making is a process we are engaged in daily as rational and autonomous beings. We have choice decisions to make on several issues of life. The fundamental attributes of a person (within the context of ‘personhood’) include his/her ability for decision making, reflective capacity and personal identity. Decision making ability is very important when it comes to such issues as participation in human experimentation. Decision making is often critically challenging to research participants, research protocol reviewers and even the relatives of research participants. Decision-making capacity requires the individual to understand the details of research and appreciate the consequence of making the decision (Zabow, 2008) thereby buttressing autonomy and the concepts of liberty and agency as discussed in the next chapter¹⁵.

3.2.1.2 Concept of decision making

The ingredients required for decision making include rationality, freedom from external forces (this is autonomy of the individual and freedom from coercion), adequate understanding of the subject matter (this is comprehension) and competence of the individual. The competence of the person or individual refers to the ability of a person to perform a task, ability to understand the type, duration, risks, benefits and procedure of research (or in clinical setting - diagnosis, prognosis, risks and benefits of treatment or procedure), ability to act or do the same thing consistently and ability to communicate concerns and choices (Afolabi et al., 2014; Zabow, 2008).

3.2.1.3 Informed consent

Informed consent is defined as ‘receiving information necessary to make an informed choice about research participation, understanding that information, and making a voluntary

¹⁵ I discuss autonomy under the ethical theories and principles in biomedical research, with emphasis on how they apply to genomic research in chapter four, section 4.4.2, p. 81.

decision on whether to participate' (Council for International Organizations of Medical Sciences. & World Health Organization., 2002). Effective and acceptable informed consent is a *sine qua non* for ethical clinical and health services research and is the key mechanism for protection of human participants in research from harm and exploitation. It is the 'moral contract' between the researcher and the study participants, and it is better appreciated as a process rather than a single action of getting a research participant append his or her signature to the consent form.

It is a process that commences from recruitment of research participants through to the research completion, as it may become necessary to seek re-consenting or utilize a tier/stepwise consent method while the research is ongoing. Research Ethics Committees (RECs) or Institutional research boards (IRBs) require that effective and voluntary informed consent be obtained before a prospective participant is enrolled in a research (Anderson & DuBois, 2012; Bean et al., 2010). The emphasis on a person's right to accept or refuse to participate in biomedical research reflects important ethical principles such as respect for human dignity and autonomy¹⁶. It is anchored on the principle of fundamental individual right to autonomous decision, and unrestricted access to pertinent and correct information that will aid in decision making (Simpson, 2010). This is the ethical reasoning for decision making and the informed consent process, thereby facilitating the prevention of exploitation of participants and patients; as well as protection of vulnerable research participants including children, pregnant women, prisoners, mentally ill patients, students and elderly people (Berger, 2011; Fisk, Beattie, & Donnelly, 2007; Simpson, 2010). The definition of informed consent highlights the essential components of this process, namely, full disclosure, comprehension, competence and

¹⁶ Autonomy and respect for persons are discussed in section two of the next chapter under the sub-heading 'Concept of autonomy' section 4.5.2, p. 78. The application of the principle of autonomy to informed consent has been alluded to.

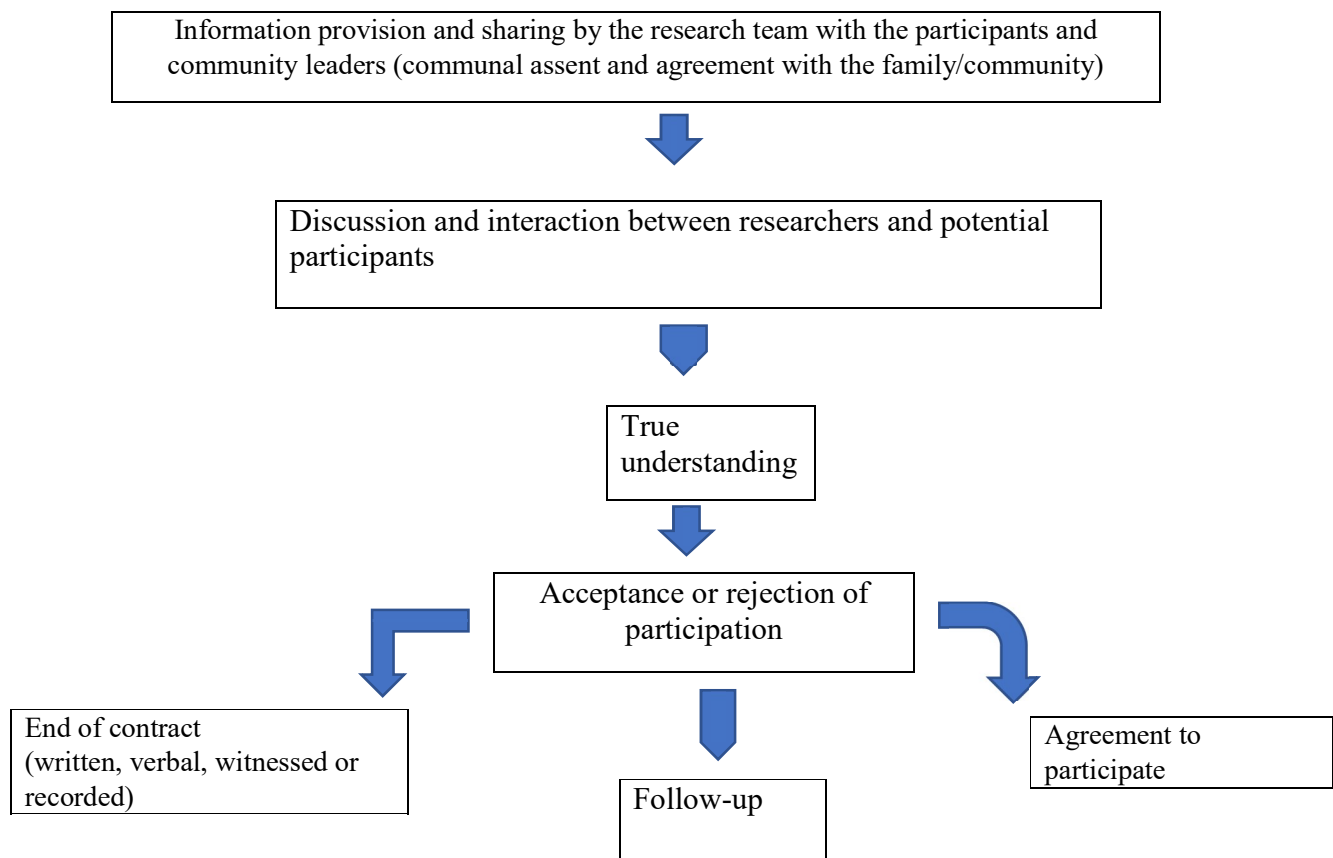
voluntariness. These four components constitute the conceptual framework for the process of obtaining informed consent, as illustrated in Figure 1 (Bhutta, 2004). I discuss each of these components below.

3.2.1.4 Core elements of Informed Consent

Full disclosure: The consent document and materials must contain adequate information about the research. It must contain information on title, purpose and type of research, names and affiliations of researchers, sponsor of research (if any), procedure (how the research will be carried out), approximate number of expected participants, expected amount of time that participants will need to commit to the research, the duration of research, anticipated risks, the social and cultural environment in which the research will take place, benefits to participants including statement about benefits sharing, how confidentiality will be maintained, clear statement that participation is voluntary and that refusal to participate does not compromise the rights of the individual, appropriate inducement or compensation for costs to participants, consequences of participants' decision to withdraw from research and procedure for orderly termination of participation (Bhutta, 2004; Robinson, Slashinski, Wang, Hilsenbeck, & McGuire, 2013; World Health Organisation, 2011).

Disclosure of information about the research is important because it minimizes feelings of coercion, and makes participants feel good about helping to enhance science and improve their own health especially if research addresses their health priorities. Sometimes information given to participants is incomplete or not properly presented, and this can adversely affect decision-making process (Izadi, Fazel, Nasiri-Vanashi, Saadat, & Taheri, 2012).

Fig 1. Conceptual framework for the process of obtaining informed consent¹⁷



This may be because researchers are not clear as to how much information constitutes ‘full disclosure’. The Belmont Commission¹⁸ stated that ‘a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided’ (National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979).

¹⁷ Source: Beyond Informed Consent by Bhutta, published in Bulletin of the World Health Organisation, 2004

¹⁸ The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research is sometimes referred to as the Belmont Commission because the commission was responsible for the Belmont Report published in 1979.

Within the ambits of the law, the researcher is expected to reveal sufficient information that a reasonable individual would wish to know in order to make a decision, but when it comes to research the participant may wish to know more about risks or benefits (Macklin, 2001). In this context, a reasonable individual means a person with an ordinary degree of reason, prudence, care, foresight, or intelligence whose conduct, conclusion, or expectation in relation to a particular circumstance or fact is used as an objective standard by which to measure or determine something (Merriam-Webster Collegiate, 1999). However, this universal understanding of reasonableness has its limitations (Tinus, 2017)¹⁹.

There are circumstances however where informing research participants of some pertinent aspect of the research may likely impair the validity of the research. This incomplete disclosure is justified only if it is clear that -

- i) it is truly necessary not to disclose to accomplish the goals of the research, for example when conducting a covert research such as the ethnographic study of gay men's behaviour (Humphreys, 1970; Tewksbury, 2002)²⁰. Critics have questioned the usefulness of researchers disguising their identities and concealing their research agendas, and that this is inexcusable form of civil betrayal that violated the individual's right not to be studied (Lugosi, 2006). But I opine that when individuals are aware of and agree to participate in such sensitive research they are more likely to change their behaviour thereby invalidating the research, this makes

¹⁹ The reasonable person is the standard of care that a reasonably prudent person would observe under a given set of circumstances. The limitations include lack of uniformity related to varying levels of reasonableness, for example applying the standard to minors (children), unskilled persons or professionals.

²⁰ These two ethnographic studies were non-participatory observational research. The researchers joined the groups of gay men, pretending as if they were gay so that they could observe the practices and behaviour of the group. Informed consent was not obtained, and the groups were not informed of the research.

incomplete or non-disclosure of information justifiable to achieve research objectives;

- ii) there are no undisclosed risks to research participants that are more than minimal; and
- iii) there is an adequate plan for debriefing participants, when appropriate, and for dissemination of research results to them.

Comprehension: The details of the research must be comprehensible to the potential participants because the manner and context in which information is disclosed is as important as the information itself, and informed consent depends on the accurate understanding of the nature and purpose of the research. The language used to prepare consent documents must be clear and intelligible to both educated and non-educated potential enrollees (contents must be translated to native languages for the benefit of uneducated prospective research participants). The documents should not be excessively long to avoid reader fatigue, loss of interest and inability to recall or appreciate pertinent information. In the preparation of consent document - unnecessary repetitions, unexplained scientific jargons and legalisms should be avoided. Also, truth dumping should be avoided. The document should be written with readable fonts and in a presentable format (Chima, 2013; Fransson, Rial-Sebbag, Brochhausen, & Litton, 2014; Jegede, 2009; Ogundiran & Adebamowo, 2010; Grietens et al., 2014). Difficulties in comprehending research information may arise if the information contains complex biomedical and genetic concepts, and if there are language barriers especially in communities with linguistic diversity and illiteracy (Beskow, Dombeck, Thompson, Watson-Ormond, & Weinfurt, 2014; Krosin, Klitzman, Levin, Cheng, & Ranney, 2006).

Within the context of genomic research, the researcher must be sufficiently knowledgeable to explain what genomics is to lay people in simple grammar or translate the concept into their language for easier comprehension. This introduces the concept of genomic literacy²¹. The level of genomic literacy of the prospective research participants may impact their understanding of genomic research, willingness to participate and informed consent process. Similarly, genomic health literacy of the biomedical researchers may reflect their competence to disclose information and level of preparedness for engaging in genomic research.

In other words, it is the responsibility of the researcher to ascertain that the participant has comprehended the information about the research. On the part of the participant, ability to understand the information, which is a function of rationality, intelligence, language and maturity, is required. Therefore it is necessary to adapt the presentation of the information to the individual's capabilities (Fransson et al., 2014; Neill, 2003; Ogundiran & Adebamowo, 2010).

Competence: The competence of the potential participants must be considered. Incompetent participants are vulnerable and so cannot be recruited except if it is obvious that they can benefit from research. The researcher must justify the inclusion of the vulnerable population²² and identify means by which informed consent will be obtained – in many cases there will be an

²¹ Hurle et al defined genomic literacy as the working knowledge of genomic science and its role in society, including personal decision-making. Genomic literacy has different facets which include genomic science literacy and genomic health literacy. The genomic science literacy is the knowledge of basic genetics and genomics concepts and processes needed to build conceptual understanding, and the necessary mathematical knowledge to support this comprehension. Genomic health literacy is defined as the capacity to obtain, process, understand, and use genomic information for health-related decision-making (Hurle et al., 2013). I use the concept of genomic literacy as the reference point for assessing the understanding of genomics and genomic research among my study participants.

²² As discussed by Henry Siverman (2011) and in the World Medical Association's Declaration of Helsinki (2012), vulnerability refers to the inability to protect oneself and can be due to intrinsic (for example deficits in decision-making capacity as in patients with dementia) and situational factors that threaten voluntary choice (for example coercive settings or undue inducements). Including vulnerable individuals in research make valid, informed consent problematic because of risks of harm and exploitation. Additional safeguards to the consent process would minimise these risks.

expectation that proxy consent (from a parent or relative) be used to supplement the consent or assent from the individual who is not seen as competent to give consent in their own right (Zulfiqar Ahmed Bhutta & Bhutta, 2002; National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979; Zabow, 2008).

Individuals who are vulnerable or incompetent by virtue of their inability to comprehend information about a research are to be excluded from research except if such research cannot be conducted on other persons (Council for International Organisations of Medical Sciences (CIOMS) in collaboration with World Health Organisation, 2002; National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979; World Medical Association, 2008). If incompetent individuals are to participate in research, the respect for persons requires seeking the permission of other parties on their behalf to protect them from harm. Such third parties should be those who are most likely to understand the incompetent persons and can act in their best interests. The third parties should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the participant if such action is in the participant's best interest (Beauchamp, 2003; Lott, 2005; National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979).

Voluntariness: Consent to participate in research must be voluntary. Unsurprisingly, voluntariness was the first principle of the Nuremberg Code, as stated in the papers of the Nuremberg trials, '*the voluntary consent of the human subject is absolutely essential*' (U.S. App. Lexis 1768, 1949, p.12). It is also the pivot of the ethical principle of autonomy or respect for persons in the Belmont Report. Research participants must be treated as autonomous beings, implying that researchers acknowledge their capacity to make informed decisions and possess rights of their

own. There must be no coercion²³. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance while undue influence is when compliance is obtained through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture (Beskow et al., 2014; Beskow, Friedman, Chantelle Hardy, Lin, & Weinfurt, 2010; Bull & Lindegger, 2011; Kamuya, Marsh, & Molyneux, 2011; McGuire & Beskow, 2010).

It is however difficult to say precisely where justifiable persuasion ends and coercion begins, but any action that involves manipulating an individual's choice through controlling their influence or threatening to withdraw the individual's rightful benefits is believed to be coercive or undue influence (Gjerberg, Lillemoen, Pedersen, & Forde, 2015; Largent, Grady, Miller, & Wertheimer, 2012).

Generation of very large quantities of bio-samples and data makes genomic research expensive therefore funders require that such bio-specimens and data be made available to other researchers to increase its utility. This has serious implications for the informed consent process because as at the time of ethical review of genomic research, the nature of potential further uses of the data and identity of future researchers are unknown, so the protection of the privacy of research participants and communities comes to the fore especially when clinical data are matched with genetic data. Therefore, the challenge that arises in biobank research is that neither the exact questions to be asked of biobank data nor who will request access to it can be fully predicted. This suggests that biobanks require either broader initial consent procedures or multiple requests for

²³ Coercion is the action or practice of persuading research participants to agree to participate in research by force or threats. In 'Ensuring Consent to Research is Voluntary: How Far Do We Need to Go?' by Bull and Lindegger (2011), the concept of coercion was further elaborated. It is unethical for researchers to unduly influence participants' free decision making by coercion.

consent over time. But these two options have drawbacks; the first is criticized as too vague to ever meaningfully be considered informed consent, while the second may impose onerous burden that creates a disincentive for biobank research. So, I opined that there may be a need for a model which considers the authorization of samples for future uses as specified by participants and overseen by an arm's length oversight body as discussed previously. I explored this ethical issue in my thesis as part of the decision to participate and informed consent process in genomic research because of their interconnectivity.

3.2.2 Peculiarities of decision-making process in Sub-Saharan Africa²⁴

In most of the indigenous sub-Saharan African settings, the concept of 'personhood' within the ethical framework of communitarianism affects decision making. A person is defined by the socio-cultural rather than by existential or psychological approach. Personhood²⁵ then refers to the ability of an individual to recognize and be recognized by the social and cultural structures of the community. Thus, personhood is seen as a social status achieved by an individual (Tangwa, 2000). Though Africans place considerable value on conformity of the individual to the social group in order to preserve the unity of human relationship (Tangwa, 1996), exceptions may exist in communities with different moral and cultural practices considering the diversity of the African race and nations. The communitarian disposition suggests communal values are very likely to affect consent process and research participation.

People necessarily make ethical decisions based not only on principles, but also on rule of thumb, short-term consequences, institutional routine, cultural notions of selfhood, religious

²⁴ Here I discuss differences in the epistemology underpinning the decision-making process between developed and developing countries. The major difference is further discussed in chapter four under communitarianism and African bioethics.

²⁵ The concept of personhood is further discussed in chapter four under section 4.5.6, p.110.

ideals, and the like. In some sub-Saharan African settings, the impact of cultural and religious beliefs become relevant when third party takes decision on behalf of research participants. The decision makers in this situation may be religious leaders and African traditional priests (for example, in Yoruba culture, they are referred to as '*babalawo*'). They are considered intermediaries between the living and the heavenly deities. The Christian religious leader or the Imam of the Islamic faith is an intermediary between the people and God, while the traditional priests serve as intermediaries between the people and the ancestors or deities such as Ogun, Sango, Orunmila, Obatala, and so on (Ogunbile, 1997).

There is a belief that Western medicine can provide neither an explanation nor a cure for certain diseases among Africans because causation is explained in terms of misfortune in the relationship between the individual and the social, natural, and spiritual environments (Chukwuneke, Ezeonu, Onyire, & Ezeonu, 2012). Therefore, people suffering from a disease whose origin has been attributed to supernatural causes, and their families, may seek explanation and possible cure for the disease at fetish shrines, diviners or spiritualists. Thus, it is not unusual to encounter communities in Africa where before a decision is taken concerning research participation or treatment options, the opinion of a religious leader or spiritualist is sought after, serving as a 'third party' decision maker (Awusabo-Asare & Anarfi, 1997). Controversies trail the concept of third-party consent common in sub-Saharan African countries, because this practice does not conform to the fundamental principles of informed consent that is autonomy and right of the individual to make a rational, uncoerced choice.

In practice, however, the responsibility of research decision making may rest with a third party even if the participant is competent in most African societies. It is important to recognize the ethical and cultural problems associated with this scenario to avoid conflicts and tensions and

appreciate the benefits so that it can be properly applied to encourage research participation while minimizing risks. It is important to stress the fact that concepts of western bioethics may be difficult to implement in our cultural setting due to ethical pluralism. Shaibu (2007) narrated his experience of conducting research in Botswana and noted the tensions and conflicts that arise from adhering to the western conceptualization of bioethics. He stressed the need to be culturally sensitive when conducting research in one's own culture. Cultural practices required the need to exercise discretionary judgment guided by respect for the culture and decision making protocols for the research participants (Shaibu, 2007). Therefore some authors have advocated that it makes sense in most societies to focus explicitly on ethical pluralism²⁶, an ideology that there are many theories about what is 'right' and 'wrong' which may be applied to resolve ethical dilemmas even when such theories are not compatible with personal or individual moral norms (Bowring, 1997; Callan, 1997; Eisenstadt, 2013; Gray, 2000), and explore how this can permeate everyday moral idioms among all the parties involved in health care (patients, families, policy makers, and clinicians) and human experimentation (researchers, participants, protocol reviewers, community elders/rulers). Though the proposal that applying ethical pluralism, that is applying all relevant ethical theories (which I discuss in the next chapter) to solve ethical issues, may help to find a middle ground for the extremes of the ethical arguments of objectivism and relativism, I opine that lack of or poor understanding of the perceptions and practice of Africans as regards research participation will result in value and ethical conflicts.

²⁶ Ethical pluralism (also known as value pluralism) is the idea that there are many theories about what is 'right' and 'wrong' which may be incompatible with one's own personal moral norms. This ideology supports the view that plurality of norms cannot be reduced to one basic norm, but there are several values that may be equally correct and fundamental, and yet in conflict with each other.

In view of these peculiarities, it has been advocated that African bioethicists should produce a rigorous normative analysis of moral experience in Africa and incorporate African views and approaches to the current bioethics debate, especially as African communitarianism²⁷ views are not influential in the global ethics mainstream (Andoh, 2011; Metz, 2007, 2010). This calls for the development of an African perspective based on principles and values centered on the existential realities of its people and provision of appropriate solutions to problems affecting research participants in Africa. This is more germane for genomic research which does not only affect an individual, but affects the entire family, and possibly the whole community. This is the rationale behind the importance and relevance ascribed to the community engagement process in genomic research which I discuss next.

3.3 Community engagement

Community engagement (CE) within biomedical research is broadly defined as a collaborative relationship between a research team and a group of individuals targeted for research. It is the process of working collaboratively with and through groups of people affiliated by geographic proximity, or special interest, to address issues affecting the well-being of those people (Centre for Disease Control and Prevention, 1997). The understanding of the culture, social norms and beliefs of the communities where biomedical research is undertaken is crucial to effective community engagement in and the eventual success of research.

The term, community participation or community-based participatory research is sometimes used interchangeably with CE. Community or public participation, a method of engaging the community, is based on the belief that those who are affected by a decision have a

²⁷ I discussed African concepts of communitarianism as well as the comparative analysis of the various types of communitarianism in greater details in section 5.2, p. 119.

right to be involved in the decision-making process. It is a two-way communication and collaborative problem-solving process with the goal of achieving better and more acceptable decisions.

Globally, increased recognition of the need to consider the ethical implications of biomedical research participants as members of a wider community, and not just as individuals, has led to active international debate on the value, goals and practicalities of involving communities in many aspects of the planning and conduct of research (King et al., 2014). Four main goals for community involvement in research have been highlighted, namely: protection; respect; empowerment; and partnership - PREP (Marsh, Kamuya, Gikonyo, Rowa, & Molyneux, 2008). These goals are especially important due to differences in social and cultural norms, values, goals, resources and technological understanding between researchers and typical participant communities. Involving communities in planning and conducting research is a means of identifying and minimizing internal risks (those only visible within a community) such as social identity and equilibrium. In addition to addressing community interests, representatives of communities can strengthen individual protection in research by supporting informed consent processes through dissemination of information on research goals, risks and benefits and incorporating local views into the development of informational aspects of research. To achieve community protection, increasing awareness of other viewpoints may help individuals to subordinate their preferences or differences to benefit a larger community.

Overall, the value of a 'relationships paradigm' for research ethics where researchers can anticipate and address the context in which communities understand risks and benefits, and individuals give consent, is recognized as a practical benefit. Community entry and information dissemination strategies need careful planning from the outset, and with ongoing consultation and

feedback mechanisms established, in order to identify and address concerns as they arise (Okello et al., 2013).

Therefore, CE is a process of inclusive participation that supports mutual respect of values, strategies, and actions for authentic partnership of people affiliated with or self-identified by geographic proximity, special interest, or similar situations to address issues affecting the well-being of the community of focus (Jones & Wells, 2007; Moini, Fackler-Lowrie, & Jones, 2005). The goal of CE is to inform, consult, involve, collaborate with and empower the community. This implies a contractual, consultative, collaborative and collegiate framework between the research team and community.

Specifically, genomic research requires community participation within the framework of alignment of traditional cultural settings of the participants and the objectives of the research. Therefore, this makes community engagement particularly relevant within the context of genomic research. For better understanding of CE, I define what a community is.

3.3.1 Definition of ‘community’

The question of how community may be defined in research has become more relevant now with the recent burgeoning of genetic research globally. Community needs to be defined in appropriate and meaningful ways. The definition of community largely depends on the nature of the proposed research, the goal of engagement and the context in which the research is carried out. It is broadly defined in relation to the geographic location of the research project and the target group to be engaged, particularly in disease specific projects. Seeley *et al* defined community as the population under study defined by a geographical area (Seeley, Kengeya-Kayondo, & Mulder, 1992) while Tindana *et al* defined community in relation to common ethnicities, languages and location (Tindana et al., 2012).

Community is a fluid concept; individuals may belong to multiple communities at any one time. A community may also be viewed as a group of people united by at least one, but perhaps more than one, common characteristic, including geography, ethnicity, shared interests, values, experience, or tradition. In an interview-based research on community-researcher relationship, Kone et al concluded that researchers must have a clear understanding of what community means to those involved in research and the respective communities themselves within which the participants reside, and emphasized that community members want to have active roles in the research process (Kone, Sullivan, Senturia, Chrisman, Ciske & Krieger, 2000). To allow for agreement among scientists or researchers when describing what a community is, the following factors should be considered:

- a. People – socioeconomics, demographics, health-status risk profiles, cultural and ethnic characteristics
- b. Location – geographic boundaries
- c. Connectors – shared values, interests, motivating forces
- d. Power relationships – communication patterns, formal and informal lines of authority and influence, stakeholder relationships, resource flows

In genomic research, the community of interest may be groups of individuals with a common disease that is to be investigated, and this community will include their family members, as family medical history and biological materials will be obtained from them for genetic analysis. At a larger scale, the community may be minority groups such as an ethnic group (for example African Americans, Yorubas of the South west Nigeria, and so on) making ethical concerns over the impact of cultural and historical backgrounds on research process more relevant.

3.3.2 Benefits of Community Engagement

Community engagement in research was borne out of the demands by community leaders, policy makers and funders for meaningful community involvement in research to address health problems facing communities. This has been shown to have many potential benefits. Community engagement in research may enhance a community's ability to address its own health needs and health disparities issues while ensuring that researchers understand community priorities. Limited understanding of, and experience with, strategies for engaging communities may militate against this benefit. Also, limited guidance on the part of institutional review boards (IRBs) or research ethics committees (RECs) on evaluating proposals for research that engages communities may result in various harms such as individual and group harms. For example, in a community where blood carries special meaning and the REC evaluating a research protocol to be conducted in that community lacks understanding of what community-engaged research is and is not guided by an ethical policy, if blood samples are collected for research, individual participants may be at risk of stigmatization within the community.

Furthermore, absence of community representatives on RECs to facilitate understanding and integration of cultural norms in research design and implementation may result in disruptions to community structure and function resulting in disagreement over aspects of a community's research participation and this may eventually lead to diminished group cohesiveness. This type of group harm was demonstrated among the Havasupai native American tribe who gave their blood samples for genetic research on diabetes but the investigators, without obtaining consent, used the same samples to study genetic factors in other diseases such as schizophrenia and to determine their ancestral lineage. The findings from these studies threatened the tribe's traditional belief of their ancestral roots (Ross, Loup, Nelson, Botkin, & Kost, 2010). Thus, understanding a

community's social and cultural characteristics as identified by community members, improves research quality, ensures the research's relevance, addresses health disparities, and enhances the research's impact (Ahmed & Palermo, 2010).

As a blend of science and art, community engagement allows the integration of scientific research and the socio-cultural setting of an environment within the framework of a symbiotic relationship (Kamuya, Marsh, Kombe, Geissler, & Molyneux, 2013). It is a relatively new component of research that is shifting the focus of research stakeholders from the traditional, narrow researcher-participant relationship to a wider interaction between the researcher and community stakeholders thus allowing for the accommodation of the opinions of the community members, their comments and perception about the research before, during and after the research (Aguilera-Guzman, Barrios, & Icaza, 2008). This helps to pre-empt problems, identify conflicts, evaluate results and share them with the community. In effect, it helps to shape the operationalization of the research in ways that the community beliefs will best meet the research objectives, and aid in preventing harms to the community. Furthermore, the participation of the community in the design of research helps to build trust between the researcher and the community, and increase participation, as it aids recruitment of study participants. It facilitates the community buy-in into the research thus enhancing likelihood of success. It also creates an opportunity for co-learning, cooperation and critical reflection among all stakeholders (Hughes, 2012). According to the Institute of Medicine, CE increases community understanding of the issues under study and enhances researchers' ability to understand community priorities, and the need for culturally sensitive communications and research approaches (Gebbie, Rosenstock, & Hernandez, 2003).

Also, CE is being encouraged to protect against stigmatization and discrimination arising out of research. Dignitary harms could arise from violation of rights or disrespectful treatment of participants and their community that is at odds with the cultural and traditional values of their community. A good example of this is the study among the Australian indigenous communities (Haga & Beskow, 2008). Research practices among indigenous Australian communities have been described as inappropriate, unacceptable, culturally insensitive, and harmful to the indigenous individuals and communities. In many instances, unethical standards were employed, with no regard for the principles and values of their culture (Gower, 2015; Taaffe, Drew, Henderson-yates, Costello, & Kinnane, 2008). This has resulted in the call for added protection for communities in biomedical research. It has been proposed that all global health research, which includes genomics research, ought to be driven by principles of equity, beneficence and social justice (Benatar & Singer, 2010).

Community engagement is beneficial to socially relevant translational research especially when the benefits of the research meet the need of the communities and the manner it is to be implemented is known (Yarborough et al., 2013), emphasizing the place of transparency in CE. Transparency encourages good relationships which are, in turn, the best conduits for the conveyance of knowledge so it behooves researchers to have a plethora of relationships that will permit them to be engaged in multiple ways with their communities. Misunderstandings and miscommunication especially with genetics research and bio-banking (Yarborough et al., 2013), such as ones reported between researchers and the Havasupai tribe (Mello & Wolf, 2010)²⁸, and

²⁸ The details of the exploitation of the Havasupai tribe of North America were discussed earlier in section 3.2.2, p. 45.

the public reaction to the Henrietta Lacks story (HeLa cells fame)²⁹ erode public trust in the research enterprise and taints community engagement in research (de Vries et al., 2014; Luque & Quinn, 2013).

Yarborough and colleagues identified several barriers to effective community engagement (Yarborough et al., 2013). These included presenting research in a way to make communities feel as though they are being used; research institutions appearing mysterious to the communities - that is the 'ivory tower' metaphor; when incentives of research are counterproductive to enduring relationships because grants that fund research that involves community participation are time-limited and restricted; and need for communities to wait a long time for benefits while researchers receive immediate rewards from research in the form of funding and career advancement, and the research institutions benefit through indirect funds, prestige and intellectual property rights. They however suggested strategies for overcoming these barriers (Yarborough et al., 2013). For example, research institutions should seek relationships with local communities and develop mechanisms for bidirectional communication before they seek their help with research projects. This may be achieved through recruitment of community advisors or community advisory boards (CABs) to each research team.

Furthermore, research institutions should promote transparency and realign rewards for researchers so that they will have incentives to establish relationships with local communities. Often, researchers ignore the power asymmetries in research. While communities exercise power over various aspects of research, the access to expertise and funding enjoyed by the researchers

²⁹ The cells of Henrietta Lack who died in 1951 were the research world's most famous human cells to grow well in the laboratory, and contributed to development of a polio vaccine in the 1950s and most recently, and international effort to characterize the genome. There are several ethical issues emerging from its continued use including issues of consent, compensation, and privacy.

creates entrenched imbalances. In this situation, transparency invites dialogue and negotiation that can strengthen relationships and research partnerships that emerge from them. Lastly, researchers should introduce measures that will make communities enjoy some immediate benefits, apart from the long-term benefits, from research. This is often predominantly encountered among marginalized communities where access to health care system is limited, further reducing opportunities to enjoy benefits of research. These communities and participants may be particularly vulnerable and suffer exploitation and abuse (Doumbo, 2005).

3.3.3 Models of ethical framework for Community Engagement

Community engagement has been proposed as an ethically important practice for global biomedical research because it helps researchers establish and maintain relationship with the stakeholders of a research program. It is concerned about the establishment of a ‘human infrastructure’ that is crucial to the success of the research. The researcher-stakeholder community relationship transcends individual participation, as it engages all members of the community whose interests would be affected by the research.

Several models for CE exist including community based participatory research (CBPR), empowerment evaluation, participatory or community action research and participatory rapid appraisal. King and colleagues (2014) proposed that community engagement is the ‘promising solution to many seemingly intractable ethical challenges in global health research’ (King et al., 2014; p.4). They proposed three concepts for this framework, namely; a) identifying and managing non-obvious risks and benefits, b) expanding respect beyond the individual to the stakeholder community and, c) building legitimacy for the research project. They opined that not all risks are obvious to researchers, members of IRBs and even the individual potential research participants. In addition, they stressed that respect for persons is demonstrated by first listening to

the community research participants to learn what their perspectives are about research and how it affects their interests. This allows them to express their concerns which can be addressed before the commencement of the research. To assert the legitimacy of a research project which is a justification of authority over the people, the researcher and community must appreciate the following –

- a. The social value of the research
- b. The nature and extent of risk imposed on the community
- c. Perceived trustworthiness of the researchers, sponsoring institution and funders
- d. Transparency of conduct of research, and
- e. Mechanisms of accountability between the research team and the affected community

The legitimacy can be built through the formal or the informal route. The formal route is through the Research Ethics Committee (REC), while the informal is through dialogue and collaboration between the researcher and the community stakeholders i.e. all those whose interests stand to be affected by the proposed research. A typical example is the trial of genetically modified mosquito to control Dengue virus transmission in Malaysia. The study was approved by the government and the local REC but the community was uncooperative because of interference with community's interests as the risks and benefits of the research were not adequately addressed before the research (Subramaniam, Lee, Ahmad & Murad, 2012). This project was developed with the goal of preventing transmission of dengue viruses by *Aedes aegypti* mosquitoes by reducing the mosquito population and/or limiting the insect's ability to serve as a disease vector. The genetically modified mosquitoes have reduced ability to transmit the virus. So to implement this project, a field site for genetic control trials had to be chosen from among a number of potential sites around the world with appropriate dengue epidemiology and

Aedes aegypti ecology (Lavery, Harrington, & Scott, 2008). This research required that the mosquitoes be released into the selected environment. This demands public engagement, anticipation of potential harms by the researchers and community consent but these were lacking in the Malaysian research.

On the contrary, the CE approach to the project aimed at eliminating dengue in Queensland Australia was perceived as effective by the program or project leadership, members of the CE team and the funders but if and why this was the case was unclear. So a qualitative study was undertaken by Kolopack and colleagues (Kolopack, Parsons, & Lavery, 2015) who identified four foundational features of CE approach, namely; a) enabling conditions; b) leadership; c) core commitments and guiding values; and d) formative social science structure. These foundations informed five key operational practices which include 1) building the CE team, 2) integrating CE into management practices; 3) discerning the community of stakeholders; 4) establishing and maintaining a presence in the community; and 5) socializing the technology and research strategy. More importantly, they could demonstrate the complexity of translating ethical intentions into effective action within the operations of CE in research enterprise.

Another attempt at formulating an ethical framework for community engagement was by the National Institute of Health (NIH) Director's Council of Public Representatives (Ahmed & Palermo, 2010; Consortium et al., 2014). The Council developed a community engagement framework that included values, strategies to operationalize each value, and potential outcomes of their use, as well as a peer review framework for evaluating such research. It is believed the use of this framework will increase accountability and equality between the partners if an authentic community-academic partnership is created and sustained through its use (Ahmed & Palermo, 2010).

The values advocated by the NIH Council include: investigators and communities must understand what community-engaged research (CER) means; community-investigator partnership should be strong; communities and investigators should share power and responsibility equitably; diverse perspectives and populations are included in an equitable manner; research goals are clear and relevant; research project results in mutual benefit for all partners; communities and investigators have opportunities to build capacity; and all partners receive equal respect (Consortium et al., 2014).

These values corroborate the views expressed by the Nuffield Council on Bioethics (2002), Emanuel et al (2004), and Chantler et al (2013) who stressed the relevance of strong relationships between the research team and the communities, equitable power sharing, capacity building, and equal respects among all stakeholders (Chantler et al., 2013; Ezekiel J Emanuel, Wendler, Killen, & Grady, 2004; Nuffield Council on Bioethics, 2002). Though Jamshidi et al opined that ‘community-based participatory research ethical challenges are of the same kind in most parts of the world’ (Jamshidi et al., 2014, p.1328), I believe there may be some discrepancies which will need enquiry. For example, the NIH Directors’ Council of Public Representatives did not address cultural sensitivity vis-à-vis influence of norms and beliefs on community ethos. The influence of culture is significant at the community interface of research hence this may need further scrutiny. According to Chantler *et al*, increasing consideration of cultural beliefs and practices of communities involved in research ‘reflects the increased attention paid to community engagement’(Chantler et al., 2013, p.31).

Another framework or model for community engagement was developed by Emanuel and colleagues³⁰, but this framework has been criticized as being overwhelming such that it may militate against conducting research in developing countries, and challenges may arise from disagreements among researchers on which ethical principle is more important among them. Emanuel et al defended their model by stating that ‘disagreeing about how to balance them in a particular case, highlights the intricacies of ethical judgements entailing multiple considerations’ (Emanuel, Wendler, Killen, & Grady, 2004; p.936).

3.3.3.1 Practical steps to making CE meaningful in genomic research

There has been a call for expansion, revision or re-consideration of a new interpretation for the human subjects’ protection principles of Belmont³¹ to account for the ways in which research affects communities, and by so doing include community protection and participation as a principle (Quinn, 2004). The basic principles of Belmont included respect for persons, beneficence, and justice. The respect for persons incorporates two ethical convictions; first that individuals are autonomous agents, and second that persons with diminished autonomy (vulnerable population) are entitled to protection. Beneficence implies individuals are treated in an ethical manner, not only by respecting their decisions and protecting them from harm, but by also making efforts to secure their well-being. This is an obligation to express beneficent actions in research by doing no harm, and maximizing possible benefits while minimizing possible harms. The third principle of distributive justice deals with application of moral requirements to

³⁰ Emanuel, Wendler, Killen and Grady in their paper, ‘What makes clinical research in developing countries ethical? The benchmarks of ethical research’ discussed eight principles and elaborated them through 31 benchmarks that systematically specify practical measures to determine the extent to which the research satisfies the principles. These principles are applicable to community engaged research with emphasis on developing countries.

³¹ The Belmont report was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research in the United States. The report summarises ethical principles and guidelines for research involving human subjects.

fair procedures and outcomes in the selection of research participants, such that participants with heavier burden should enjoy greater benefits of research (Bruner et al., 2006; Hedgecoe, 2004; Lott, 2005). These three principles do not adequately cover communities' or groups' protection hence the call to include community participation as a principle.

As previously discussed, the robust approach to achieving community protection is to get the community representatives involved in research from the genesis of the protocol to the publication of the research findings. A practical approach is for researchers to utilize the existing political or social structure within the communities³². For example, a case study on aligning community engagement with traditional authority structures in global health research in northern Ghana showed that specific pre-existing features of the community greatly facilitated community engagement and the use of traditional engagement mechanisms limits the social disruption associated with research conducted by outsiders (Tindana et al., 2011). For the sub-Saharan African setting, a community advisory board (CAB) has been proposed as an appropriate method for CE especially for genomic research because of the 'potential implications of research findings drawn from individual participants on the larger communities they represent'(Campbell et al., 2015, p.1). I briefly discuss what a CAB is.

CAB is a group of people representing the community targeted for research who liaise between the research team and that community. The board has the potential of strengthening the science of research study through improving informed consent materials and procedures, enhancing recruitment procedures and managing the research-related risks to participants and their community during the research process, and all these are instrumental goals of CE

³² This was the point addressed in section 3.2.2, p. 45 about the research conducted among the Havasupai tribe of North America. The failure of the researchers to make use of the existing traditional structure of the tribe resulted in internal conflict and distrust among the members of the community and the research team.

(Haldeman et al., 2014). The CAB provides a unique insight into the social and cultural context within which the community operates. Intrinsic goals of the CE include respect for a community's traditional beliefs, understanding of illness, and help-seeking behaviour relating to illness.

Successful CE depends however on the degree to which CABs legitimately represent and engage with communities targeted for research (Simwanga, Porter, & Bond, 2018). A study that investigated the contributions of a researcher-driven, population specific CAB in a genomics research project involving schizophrenics in South Africa (Campbell et al., 2015), revealed that CAB gave invaluable input on the consent processes and recruitment strategies, as well as suggest ways of minimizing the potential for stigma and discrimination. Furthermore, the CAB also promoted the respect and dignity of research participants and their community by ensuring sensitivity and respect of the community's traditional beliefs about schizophrenia and its treatment.

But the challenge in CE has to do with whether CABs are community or researcher-initiated, and representative of either very broad community groups or specific groups such as patient communities. The former tends to be community initiated, promoting the autonomy of its members as advocates and the rights of the community. The drawback is the challenge of generating resources and funding to support sustainability. The alternative is a population-specific model that means representing the needs of a specific group of people. This model tends to be research-team initiated and funded, and provides a voice for the targeted population. This type of CAB contends with the challenge of maintaining the independence and autonomy of their members on one hand, and managing the input from community members who may be unfamiliar with biomedical research on the other. Sustainability is also an issue here because funding only

lasts for the period of research. Trust and rapport take time to build. Sometimes the CAB may not represent the broader community (Van der Elst et al., 2014).

The models I discussed above were attempts to make community engagement addresses ethical dilemmas by establishing collaborative partnership between communities and researchers. The effectiveness of these models however needs to be assessed and refined to make them applicable in different research settings.

3.3.4 Community engagement in research: The sub-Saharan African scenario

The sub-Saharan African society is characterized by ethical multiculturalism, a situation that does not infer entirely different cultural backgrounds as the different ethnic communities share some common beliefs and moral values (Tangwa, 1996)³³. The recognition of this fact undergirds culturally appropriate and ethically responsive decisions. The various African societies have norms and moral ethics which are founded basically on communitarianism. This is shown in the processes of and procedures for social interactions, decision making and communal relationships. Within this concept, individual rights and autonomy contribute to the overall community stance and decisions over research participation or treatment acceptance or refusal, are subjugated to the community decision (Tangwa, 2000). The community focuses on actions that best promotes its interests and not the individual. The community decision makers, referred to as the ‘gatekeepers’, present the community position on consenting to research (Jegede, 2007). They serve this function with the objective of protecting the individual members of the community from exploitation, harm and risks (Jegede, 2009).

³³ The concept of communitarianism believed to typify African ethics is discussed in the next chapter under Communitarianism (section 4.5.6, p.107), highlighting the views of such writers like Callahan, Amitai Etzioni, and Andrew Jason Cohen.

There is no doubt that CE strategies and skills can build trust and reduce historical mistrust between researchers, communities and populations being studied, as well as contribute to the quality of study designs, methods, and dissemination of findings (Brenner & Manice, 2011). When researchers fail to consider the concerns and needs of participants, even morally unproblematic health disparities and health services research might fail to meet ethical benchmarks and also fail to translate potentially beneficial interventions into practice (Lynch & Mitchell, 2010).

The methods of CE often depend on the goals of engagement, the research context and level of engagement. Information sharing is crucial to CE. Two types of CE were identified; direct engagement and through representatives. Direct engagement entails town hall or community meetings (called ‘durbar’ in Ghana and ‘barazas’ in East Africa), which are often attended by various categories of people and the number depends on the research setting. It is a forum to receive first-hand information from the research team, open a dialogue, and rehearse effective provision of complex information on genomic research which later informed the individual consent process. Another method of direct engagement is focus group discussions, and this involves fewer people such as meeting with women’s groups, community leaders, community development officers or patients with specific disease of interest.

Engagement through representatives include the constitution of CABs. Two models of CAB were recognized; broad community and population-specific models³⁴. The broad community model is characterized by selection of community members including elders and opinion leaders with adequate knowledge of the community’s cultural values. The population-

³⁴ This differs from the afore mentioned researcher- or community-initiated CAB under section 3.3.3.1, p. 60. The broad community and population-specific models of CAB mentioned in this section are community-based models.

specific model entails selection of community members who share similar characteristics (for example, the disease of interest, gender or age-group) with potential study participants.

Therefore, researchers should make CE strategies flexible to change as the research project and the engagement needs develop bearing in mind the need for cultural sensitivity and intimacy.

Despite its relevance to achieving CE goals of building trust and partnership, few studies have demonstrated the potential value of CABs in strengthening interactions between a research institution and a local geographic community through contributing to meeting intrinsic ethical values such as showing respect, and instrumental values such as improving consent processes in sub-Saharan Africa (Kamuya, et al., 2013; Simwinga, Porter, & Bond, 2018).

A review of the existing literature published on CE strategies for genomic studies in Africa, that used CE, CABs, community consultation, community participation, effectiveness, genetic research, genomic research, Africa and developing countries as search criteria between October 2003 and May 2014, concluded that there were several CE strategies that could support genomic studies in Africa, most of which targeted early stages such as recruitment process. This finding showed dearth of information on CE in genomic research in Africa, buttressed the need to identify effective strategies to engage research participants and their communities beyond the recruitment stage especially how the views of the local communities should be incorporated into future uses of human biological specimens to determine the most effective models in the African settings (Tindana et al., 2015).

In terms of selection of communities' representatives, they are identified internally or externally in CE activities, individuals might be selected or select themselves to speak on behalf of a particular community, where their views reflect those of their communities through being typical of other community members. Such individuals may be identified on the basis of

characteristics such as where they live, their education level or their religion. They are relatively charismatic, well known, and outspoken such as leaders of women's groups or religious elders (Kamuya et al., 2013; Marsh et al., 2011). Sometimes they may be less well known and vocal, but may have greater contact with, and awareness of, everyday issues and concerns in their communities, including those of the most vulnerable and marginalized members. In the discharge of their duties, CABs are faced with tensions from the dual functions of both advancing the research and protecting the community, dual functions that can potentially conflict with one another. The type of conflicts encountered and CE strategies employed to resolve them differ based on the study site, the socio-cultural complexity of the research setting and the existing local administrative structure that may influence the conduct of research.

The recognition of the importance of community-based participatory research (CBPR) in multi-cultural and multi-ethnic settings necessitated the constitution of community advisory boards by the principal investigator as a mandatory requirement for conduct of research involving communities in Nigeria. It is however not clear how the community representatives would engage in genomic research as there is no study at present that has evaluated this. Would they allow community participation in genetic or genomic research? What type of informed consent process will be acceptable to them? Will bio-banking, export and future analysis and sharing of samples of community members be acceptable? These are questions that I sought to answer with my thesis. Furthermore, these would require evaluation vis-à-vis the meaning of research by the community leaders, what their understanding of genomic research is, what is their standpoint in their communities' participation after learning what the genomic experimentation procedures entails (that is the donation of biological materials), and what their stance would be on receiving information on export of these materials for analysis in overseas centers.

In conclusion, the growing appreciation of the role of community leaders and families in the context of decision-making in and successful implementation of genomic research has made community engagement an important ethical requirement. The socio-cultural diversity and beliefs are potential factors that create tension and dilemma in the researcher-participant or researcher-community relationship. This can however be resolved by effectively engaging the targeted communities at the planning stage of the research and sustaining their participation throughout the research process. The strategies for implementation of community engaged research are still unclear, though there have been several ethical frameworks, but these are yet to be proved effective and acceptable in sub-Saharan Africa.

Having discussed the informed consent and community engagement processes in genomic research in this chapter, I briefly discuss other ethical issues encountered in genomic research which I did not directly address in my thesis, though I refer to them while discussing informed consent processes.

3.4 Supplementary ethical issues

3.4.1 Privacy and confidentiality

A right to privacy is a right to control access to, and uses of, personal information. It is a normative concept, as it is understood in terms of rights of privacy granted an individual. In effect, when an individual restricts access to self and to personal information, then a condition of privacy obtains. Confidentiality is privacy protection, in which the duties of the one who has gained access to personal information about another person has a clear duty not to pass on the information to outsiders, or use it for other ends than the one agreed upon (Ursin, 2010).

The UK and International guidelines on human genetics and genomics research emphasise that researchers must consider issues of ensuring confidentiality of results, respecting autonomy

and privacy, social and cultural differences, providing appropriate information to participants, obtaining informed consent, and offering appropriate compensation for participation (Roy Choudhury & Knapp, 2006). This puts the responsibility of confidentiality on the researcher.

To achieve confidentiality, bio-sample must be either anonymised or given a unique identifier (coded) (Abayomi et al., 2013). Coding is advocated because it allows some control over the sample by the donors, who may decide to withdraw their samples since they can be identified. However, the usefulness of biobanks is that it combines genetic and health data so anonymity would limit this utility. (Auray-Blais & Patenaude, 2006; Hobbs et al., 2012).

Privacy risks have been identified as a potential barrier to engaging the public in genomic research. For example, a review of Pan-European studies on people's willingness to participate in genomic research showed that trust, privacy and data security are concerns expressed by the participants (Gaskell et al., 2013). In another study, lack of privacy was associated with unwillingness to participate in biobanking research among Jordanians (Ahram, Othman, Shahrouri, & Mustafa, 2014). However, there are contrary views expressing participants' limited concern about privacy and confidentiality, should they choose to participate in bio-banking research (Pullman et al., 2012). For example, the analysis of data from 18 focus group discussions conducted in Austria, Finland and Germany showed that instead of privacy the notions of control and controllability of biobanks are most essential for people (Snell, Starkbaum, Lauss, Vermeer, & Helen, 2012).

The critics of privacy in biobanking have stressed that for bio-banking research to be beneficial and meaningful, personal health data must be matched with individual bio-specimens. Also, that rights accorded human participants do not necessarily extend to biological samples. Until half a decade ago when substantial changes were made to the Common Rule in the United States,

much of the research on bio-samples were conducted without consent because bio-banking research was not considered ‘human subjects’ research. Now a written consent is required for bio-specimen research, even if they have been stripped of identifiers or initially collected for a non-research purpose because of the personal and group harms associated with biobanking research (Williams & Wolf, 2013).

Though I do not specifically explore the views of potential research participants or biomedical researchers on privacy and confidentiality in my thesis, I look out for views and responses that suggest its significance in genomic research participation as an incidental finding.

3.4.2 Capacity building

It has been observed that the poor genomics research capacity of sub-Saharan Africa could prevent maximal benefit from the application of genomics in the practice of medicine and research on the continent, and this calls for an urgent need for capacity building (Adedokun, Olopade, & Olopade, 2016). The capacity building is not just in the science of genomic research but also in the ethical oversight of this type of research globally, and particularly in sub-Saharan Africa. For example, there has been a clamor for research organisations to train African researchers, bioethicists and social scientists thus building genomics research capacity and capability in Africa, and to fund the establishment of biobanks and the genomic analyses platforms within Africa (Dandara et al., 2014; H3 Africa Working Group on Ethics, 2017). Also, the need for capacity building of research ethics committees that have limited familiarity with genetic and genomic research, and acceptability of downstream uses of genome wide association data have been identified (Tindana et al., 2015; Tindana et al., 2012).

Therefore, the ethical justification of building capacity for science and ethics of genomic research has remained at the vanguard of majority of international collaborations and initiatives (Ogundiran, 2004; Silaigwana & Wassenaar, 2015). For example, one of the cardinal goals of the

H3Africa Initiative is promoting genomic research on the African continent through capacity development (Ramsay, 2015). This goal has been boosted by recent improvements in research funding and infrastructural support. In addition, these contributions are leading to the establishment of world-class research facilities, biorepositories, training programmes, scientific networks and funding schemes to improve studies into disease and health in Africa (Karikari, Quansah, & Mohamed, 2015).

Emanuel and colleagues (2004) emphasized the importance of capacity building as a component of ethical principles and benchmarks for multinational clinical research when they included it as an integral part of what makes clinical research in developing countries ethical (Emanuel et al., 2004). Similarly, the WHO urged its member states to strengthen existing, or establish new centers and institutions, engaged in genomics research with a view to strengthening national capacity and accelerating the ethical application of the advances in genomics relevant to countries' health problems (WHO, 2004). Capacity building is not one of the issues I address in my thesis although I explore the level of preparedness of biomedical researchers for genomic research.

3.4.3 Feedback of research findings to research participants and communities

There are controversies about feedback of results of genomic tests to research participants and communities, and what results to feedback. Some of the valid concerns about return of genomic research results include returning results which have not been clinically validated, and the fact that most genomic research aims at improving health care by advancing knowledge rather than directly impacting a study participant. Several arguments in favour of returning results are based on the principle that participants have the right to receive results associated with the use of their bio-specimens, but there is need to distinguish between an unexpected result that is clinically relevant, analytically validated, actionable and directly related to the objective of study, and an incidental

finding which has potential health importance found in the course of research but beyond the aims of study (Marodin, França, Rocha, & Campos, 2012).

It has been advocated that communities deserve full disclosure of research findings, and that depending on the nature of the research and types of data being collected, the research participants and communities involved in population-based research may be provided with feedback that occurs immediately, at an intermediate stage, and at a later stage when a more comprehensive understanding of the study findings is available (Marshall & Rotimi, 2001). In the African context, the challenges encountered in results feedback include the validation of research findings in a diagnostic facility, absence of health care specialists trained in genetic counselling that could provide feedback, controversies on what findings can be considered actionable, and lack of national policies on SOPs for feedback of genomic research results (H3 Africa Working Group on Ethics, 2017). Overall, empirical research on the attitudes, values and beliefs of research participants about receiving the results from genomic studies are limited (Middleton, Parker, Wright, Bragin, & Hurles, 2013).

3.5 Conclusion

I do not directly address these supplementary ethical issues in my thesis, for example feedback of results to research participants because of the technicality involved in communication of genomic results that makes its exploration complex in empirical studies, and the universal acceptance of existing guidelines on feedback of results which may be adaptable to the sub-Saharan African setting. Nevertheless, I consider these supplementary ethical issues in my thesis as incidental findings when they were referred to by my study participants.

The ethical concerns of informed consent, community engagement, collection, storage, export and secondary use of bio-specimens, and complex issues concerning preparedness of

researchers to engage in genomic projects are my emphasis. I explore these concerns among potential research participants and biomedical researchers to understand their opinions and perspectives. I discuss the ethical principles and theories underpinning these ethical issues in the next chapter.

CHAPTER 4

Ethical Theories and Principles Applicable to my Research

4.1 Introduction

This chapter is divided into two sections. In the first section, I discuss the ethical theories which are applicable to my research, including key ethical theories such as principlism, which have been applied to ethical issues in genomic research (de Vries et al., 2011; Ramsay, de Vries, Soodyall, Norris, & Sankoh, 2014), and therefore are pertinent to my thesis. In the second section, I discuss the concepts and critiques of communitarianism, liberal individualism and autonomy. These are ethical theories based on key ethical principles like respect for persons, justice and benevolence which were discussed in the preceding section. I applied these concepts to understanding decision-making and consent process, as these ‘ethical theories describe the meanings of moral language in everyday discourse, and the schema in moral standards or sets of rules’(Howell, 2010, p.3), thereby contributing to normative analysis of the views and perceptions of research stakeholders including potential research participants and biomedical researchers who constitute my study participants. I also applied this literature review to the interpretation and discussion of the theoretical background of my findings.

Section One

4.2 Ethical Theories Applicable to my Research

The ethical issues encountered in research are evaluated and often discussed based on fundamental ethical principles and theories. This is important to my thesis because the issues of informed consent and community engagement in genomic research, the two ethical concepts which are the focus of my research, have been explained from the normative framework of existing ethical theories which function as guides for moral reasoning and justification for moral actions. Though reasoning involves the use of abstract thought processes to solve problems and to

formulate plans, moral reasoning however is concerned with making decisions on how humans ought to be and act (Ogundiran & Adebamowo, 2010; Wasserman, Stevenson, Claxton, & Krug, 2015). In turn, the basis of decision making process in humans rests on the foundations of ethical theories which ‘help people to discern commonplace morality and strengthen moral judgements in the face of moral dilemmas’ (Rich & Butts, 2014, p.110).

I approach my discussion of the ethical theories by first discussing communitarianism, principlism, feministic ethics and ethics of care, then comparing and contrasting liberal individualism and communitarianism. These ethical theories have different normative core values, for example the ethics of care highlights care; feministic ethics emphasise empowerment, and equal and just treatment of women, principlism projects the ethical principles of benevolence, non-maleficence and justice, and communitarian ethics stresses solidarity, brotherhood and communal good (Howell, 2010; Rich & Butts, 2014).

4.3 Relevant ethical theories

4.3.1 Communitarian ethics

At the heart of communitarian ethics is the view that an individual is ‘embedded in a context of social relationship and interdependence, but never an insulated person’ (Ogunbanjo & Knapp van Bogaert, 2005: p 1). Communitarianism stresses the significance of social bonds and the balance between individual rights and social responsibilities, such that social order and liberty are mutually supportive and reinforcing. Generosity, compassion, solidarity and social well-being constitute the ethical values of communitarianism while its social values include harmony, stability, mutual reciprocity and sympathy.

4.3.1.1 Communitarianism – its ethical philosophy

It is a philosophy that upholds the concept of the welfare of the society as a whole, with foundational values of the collective good, common interests, solidarity, reciprocity and mutuality. This concept anchors the well-being of the individual and his or her identity within the social networks of the community. In other words, the communities build individuals just as much as individuals build communities (Etzioni, 2011; Gross, 2014; Stephen Macedo. 1, 1991). The individual therefore cannot engage in deliberative actions without prior consideration of communal interest. So, communitarians disagree with the classical liberals that the individual autonomy is superior to communal values.

Communitarianism focuses more on the common good and public interest than on autonomy, and emphasizes the fact that many bioethical issues cannot be reduced only to questions of individualism and choice (Bowring, 1997; Little, 2002; Woog, 1993). For example, the ethical issues of genetics and reproduction often touch on community values, its social institutions and the society as a whole. So, I opine there is need to take social implications seriously in ethical analysis and not simply assume that only autonomous decisions of individuals are of importance.

In communitarianism, man is perceived as a social animal, not isolated individual, whose life is within a sphere of deeply penetrating social, political and cultural institutions and practices. There is no clear distinction between the private and public spheres, the private can be protected but what counts as private will be a societal decision not something inherent in human condition. Ogunbanjo and Bogaert identified two forms of communitarianism in Africa which are radical and moderate communitarianism (Ogunbanjo & Knapp van Bogaert, 2005). Radical or authoritarian communitarianism emphasizes the fact that the community defines a person as

person (and not some isolated property such as rationality and free will), and that personhood is acquired – an individual's moral achievements earn him or her the status as a person, a full member of the community, and personhood is something at which an individual can fail if he does not perform his moral obligations to the community as explained earlier. Moderate communitarianism on the other hand emphasizes more of the group than the individual. It sees the society not as an aggregate but rather as a community of individuals. Community life, which is common to both types, is a robust feature of the African communitarian society and it mandates an ethics that is weighted on duty to others and to the community. It is this social life that constitutes the foundation for moral responsibilities and obligations.

4.3.1.2 Communitarianism and African bioethics

The ethics of a society is embedded in the ideas and beliefs about what is right or wrong, what is a good or bad character. It is also embedded in the conceptions of satisfactory social relations and attitudes held by the members of the society which bring about social harmony, fairness, justice and mutual cooperation. In the past, European writers had expressed non-existence of moral and ethical principles in Africa. For example, Nadel stated, concerning the Nupe tribe of northern Nigeria, that 'as for the realm of ethics, Nupe religion is altogether silent. It upholds no ideal man or condemns his antithesis. There is no eschatology, no mythology, exemplifying rights and wrongs, crimes and retribution, and no promise of reward to the law. Nor is there formulated doctrine concerned with norms of actions or more common currency, the simple rights and wrongs or everyday morality' (Nadel, 1954: p 265). These assertions by the early Europeans, which were used to justify the strong judgement about the African morality and ethics as being non-existent or crude, were likely due to lack of understanding of the African culture and ethics.

On the contrary, there were European writers such as Tempels who observed that ‘Africans have traditionally been very conscious of the social dimension of morality, which is seen in social context, hence any violation of the moral order has a social aspect which involves serious consequences. The whole society is affected, for every evil act is an anti-social act which has adverse effects on the whole community’ (Tempels, 1959: p 45). Likewise, African scholars have shown in their studies that a well ordered and clearly defined system of ethics and morality existed in Africa before colonisation. They provided evidence that African societies have a deep sense of right and wrong, a moral sense that produced customs, rules, laws, traditions and taboos which can be observed in each society (Mbiti, 1969). The appreciation of this traditional African ethics and culture by African scholars resulted in the rise of black consciousness and the acceptance of the notion that blackness is not a sign of inferiority. Subsequently, African peoples realised that traditional African ethos and morality have important roles to play in the moulding of a humane society where peace, solidarity and brotherhood will thrive. So, with reference to medical research, they began to re-appropriate the medical knowledge gained over centuries by traditional medicine and medical practice.

The reality of an African bioethics appears problematic due to value and cultural changes that foreign values introduce. The challenge is that foreign values might advocate principles that clearly cannot capture core aspects of African values and hence makes it appear ‘too western’. This situation causes tension and creates conflicts in Africans’ conception of ethics and empirical experience as modernity continues to gain a dominating impact on African life. It is necessary to understand that African ethics is rooted and flows from Africa’s innate traditional values. These traditional values are important for moral decision making. The African ethical values which have been highlighted by African scholars include, communality of life or communalism which

‘ranked over and above individualism’ (Wiredu, 1983), solidarity which is interpreted to mean ‘African man’s concern for the well-being of his brother and neighbour’ (Udokang, 2014), retribution or justice which refers to ‘consequences of one’s actions’ and morality or good character (Abogunrin, 1986; Divine, 1986; Gbadegesin, 1991). According to Gbadegesin, ‘African ethics is a character-based ethics, an ethics that maintains that the quality of the individual’s character is most fundamental in our moral life’ (Gbadegesin, 1991; p.). These values form the core basis for any ethical deliberation on issues related directly to African tradition. The central value of the African ethics however is communality, what has been referred to as ‘African communitarianism’.

The South African Zulu’s Afrocentric approach to bioethics has been used to illustrate the concept of communitarian ethos that typifies African bioethics. ‘Ubuntu’ is an African philosophy which for many years has anchored and shaped the African way of living. It is a recognized African concept which anchors African communities. It is a concept that promotes oneness and togetherness. The South African Zulu maxim ‘*umuntu ngumuntu ngabantu*’ means ‘*a person is a person through others’ meaning*’. This means that for a person to flourish, his success can only come through the support of others. Ubuntu is about the community (Metz, 2007).

In most traditional African settings, the individual does not and cannot exist alone except corporately. They owe existence to other people, including those of past generations and their contemporaries. Whatever happens to the individual is believed to happen to the whole group, and whatever happens to the whole group happens to the individual. This is the cardinal point in the understanding of the African view of man (Mbiti, 1969). It is a model of political organisation that stresses ties of affection, kinship, and a sense of common purpose and tradition.

Personhood³⁵ is not wholly defined by membership to a community. According to Gbadegesin (1991), in the African perception persons become persons only after a process of incorporation. This conception of personhood implies a distinction between the concept of human being and the concept of a person: an individual can be a human being without being a person. This concept is believed to be central to 'African communitarianism' (Gbadegesin, 1991; Wiredu, 1983).

The family is the primary social unit and plays a central role in an individual's life. In this light, the family is responsible for the well-being of its members especially the aged, sick, disabled and the unemployed. African morality is based on beneficiary values of collective family and community well-being, without dissolving the individual's character. The community empowers 'personness'. Community is the basis for morality in that it guarantees the well-being of both the individual and the community. The construction of moral knowledge in African indigenous communities relates to their mode of understanding reality and within this reality, the well-being of the community is the central concern. So, a visitor to Africa is soon struck by the frequent use of the first personal plural 'we', 'ours' in everyday speech. Community refers to all life i.e. animals, the habitat (land), flora, and even the elements. It also includes the ancestors and those not yet born. The success of life is found in the ability to maintain a healthy relationship with all.

From the perspective of communitarianism, African traditional bioethics differs from Western bioethics which promotes individual autonomy. However, this does not mean that developed western communities do not embrace communal values such as collective responsibility, cooperation, interdependence, mutual helpfulness and reciprocal obligations; just

³⁵ I discussed the concept of personhood earlier in sections 3.2.1.1 and 4.3.1.2, p. 28 and 68 respectively.

that individual autonomy commands greater importance. This can be illustrated using the practice of medicine in which the individual patient's good is at the centre of nearly every discussion hence it is overwhelmingly non-communitarian and rarely concerns itself with the common good. On the contrary, African communitarian approach regards personal rights such as rights to health care in a communal context. African culture places considerable value on conformity of the individual to the social group.

Also, in Western society, a decision to participate in a research is personal even when the individual discusses it with family members or friends. Ultimately, it is the welfare and interest of the individual that constitute the overriding consideration. However, in African ethics an individual's decision is determined by how and to what extent the consequences of an individual's participation in research affects the community. This does not remove from the ethical individuality of the human being in African ethics, as human individuality is not swallowed up by the sense of communalism. Rather the authoritarian nature of African custom, which is supposed to be respected and obeyed uncritically, places considerable value on the conformity of the individual to the social group. So the individual is the centre of human relationship and also contributes to its sustenance, possessing an ethical status and sustaining the entire social spectrum of the community (Mbiti, 1969; Udokang, 2014; Wiredu, 1983).

As far as most African communities are concerned, the reality of the communal life takes precedence over the reality of individual life histories, whatever these may be. And this primacy is meant to apply not only ontologically, but also in regard to epistemological accessibility. This concept of communitarianism underpins the understanding of the cultural background of research participants with regard to how informed consent is obtained. Ethical conflict is likely to emerge when researchers and participants come from different cultures, or when a researcher who is from

the same culture with the study participants fails to consider the culture and customs of the participants. In a culture where a person sees himself as an extension of his family or community in Africa, serving as an intermediary between ancestors and future generations, insistence on individual informed consent in group-oriented cultures is viewed as morally unacceptable and this can negatively impact research and its benefits (Mbugua, 2009). The failure of researchers or research sponsors to recognise the ethics and culture of the study participants can adversely affect the recruitment of potential study participants and implementation of the research, resulting in hindrance to medical advancement.

For example, the success of the HIV prevention trials in Nigeria and Tanzania, and the progress recorded so far in the HIV vaccine trials in South Africa have been associated with effective engagement of the communities in these three sub-Saharan African countries (Slevin, Ukpong, & Heise, 2008). The researchers and their sponsors respected the cultural practices of the study participants and engaged the communities in all phases of the research. It is for this reason that the Nuffield Council on Bioethics recommended that informed consent process be contextualised within the cultural practices of the developing countries where research is hosted by emphasising the role of the ‘community gatekeepers’. The report stated that agreement must be obtained from community and possibly assent from senior family members before prospective research participants are approached (Nuffield Council on Bioethics, 2002). Similarly, the World Health Organisation’s Operational Guidelines for Ethics Committees that review biomedical research and the Council of International Organisation of Medical Sciences (CIOMS) ethical guidelines emphasised this concept (Council for International Organisations of Medical Sciences (CIOMS) in collaboration with World Health Organisation, 2002; World Health Organisation, 2000).

So, by implication, conducting a research in developing African countries demands a community engagement process that incorporates the African ethics of communality, concept of personhood that is based on communitarianism and consent process that recognises the roles and impact of the community. It is against this background that I chose to investigate the consent process and community engagement in genomic research in a developing sub-Saharan African country, Nigeria.

4.3.2 Principlism

Principlism uses a set of ethical principles drawn from common shared conception of morality. This theory was popularized by Tom Beauchamp and James Childress in 1979 (Beauchamp & Childress, 2012). This principle-based ethics was influential because of the four *prima facie* principles upon which it is based. These principles are not absolute. They are autonomy, beneficence, non-maleficence and justice. Autonomy³⁶ is concerned with respect of persons i.e. respect for the choices competent people make. Beneficence is our obligations to help others always provided the costs are not too high while non-maleficence means not to harm others. Justice is an important requirement that deals with fair and equitable distribution of research risks or burdens and benefits. These principles are closely associated with rule-based ethics and provide a framework to support moral behaviour and decision-making (Azétsop & Rennie, 2010).

Principlism has two key virtues, first it reflects the liberal, individualist culture from which it emerged, thus it is culture congenial, and second it is relatively simple in its conceptualization and application making it attractive to clinical decision making. Because of the

³⁶ The concept of autonomy is discussed in Section 2 of this Chapter. Here it is alluded to because of its relevance to principlism – the principle of respect for persons that has autonomy at its core

individualism underlying principlism, it gives prominence to autonomy. Also, the other components of principlism appears to lead to autonomy, for example non-maleficence implies a right not to have our mind or body harmed by another, that is to be left intact, and this is a historical variant of autonomy³⁷. Similarly, the point of treating people justly, or allocating resources to them in an equitable manner, is to allow them function as autonomous persons, not discriminated against or harmed by inequitable treatment (Callahan, 2003).

Respect for persons or autonomy has tended to be the leading principle of research ethics or biomedical ethics respectively. This principle historically has its roots in the liberal moral and political tradition of the Enlightenment in Western Europe (Azétsop & Rennie, 2010) and is dependent on two essential conditions; *liberty* which specifies the independence from controlling influences, and *agency* referring to the capacity for intentional action. Autonomy identifies actions that are protected by the rules of informed consent, informed refusal, truth telling and confidentiality.

The principle of justice underpins the selection and recruitment of participants for research, ensuring that they do not bear burden of research that is not commensurate with the benefits that accrue to them from same. In healthcare, justice underpins the equitable share of resources and protects from exploitation. The proponents of principlism argued that we should all be able to acknowledge the four principles as they are of moral values but the critics pointed out the lack of hierarchical order thus failing to guide our actions and offer reasons why we do what we do (Beauchamp, 2007; Brown, 2009). Nonetheless, these four principles have been applied to

³⁷ The historical link of autonomy with non-maleficence is related to the notorious Nazi experiments of the second world war and the Nuremberg trial that gave birth to the Nuremberg Code (Weindling, 2001)

resolving ethical dilemmas in genomic research, especially bio-banking of human samples and data. So, I applied principlism to the discussion of my findings.

4.3.3 Feministic ethics

Historically, feminist ethics developed in strong opposition to the traditional male-oriented approaches which appealed to universal moral rights and principles such as deontology and utilitarianism (DeVault & Gross, 2007). Feminist ethics is context-sensitive with core values of responsibility, relational autonomy, care, compassion, freedom and equality. The social and political background of feminist bioethics is feminism and feminist theory with its major goal of ending the oppression of women and to empower them to become an equal gender. This is against the background of women being allocated social roles that leave them worse off with respect to benefits enjoyed by men, such as freedom and power. Apart from differences in reproductive roles, women share many morally relevant characteristics with men such as rationality and capacity for suffering, thus they deserve fundamental equality (Killmister, 2013; Lohm & Kirpitchenko, 2016).

Furthermore, several authors have observed that the feminist ethicists emphasize equal and just treatment of women to fight against discrimination. Through the activities of feminist ethicists, ethical issues such as reproductive medicine; justice and care; genetic diagnosis; sex selection; contraception and HIV; equal access to healthcare and healthcare resources; cultural issues; and global bioethics began to command greater importance (Breckenridge, Jones, Elliot, & Nicol, 2012; Mackenzie & Stoljar, 2000). Contrariwise, critics doubted the utility of feminist ethics as a well-equipped and full moral theory because of its dualistic way of addressing ethical issues and at the same time stressing a feminist viewpoint, for example the difficulty in harmonizing feminist bioethics and global perspective of ethics (Shields & Serna, 2011).

As regard research participation, I surmised that feminist ethics becomes relevant in cultures where women are relegated in decision-making process of issues that involve them. For example, the authoritarian communitarianism³⁸ of most sub-Saharan African countries that confers the man, the head of the family, with authority to decide whether the wife should participate or not in research or access healthcare that will benefit her is applicable here. In genomic research participation, the gendered views and opinions to consent process and participation and how cultural norms affect their perceptions may be relevant therefore I explored this in my thesis.

4.3.4. Ethics of care

Though the ethics of care evolved from feminist ethics theory, it has become more refined and sophisticated. So, I chose to discuss it separately. Ethics of care is based on relational ontology, depicting the comprehension of the moral agent, not primarily in terms of independence, equality of power and influence, but rather as mutually interconnected, reciprocal, vulnerable and dependent. This comprehension makes room for intimate and private relationships, as well as public ones including groups, institutions and communities and indeed countries (Pettersen, 2011; Pols, 2015). For example, instead of depicting communities or nations as sovereign, self-sufficient and equal in strength, we can envisage them as relational, mutually dependent, and unequal in power and resources.

The ethics of care emerge from women's care work, including maternal work. Feminist care ethicists do not sentimentalize work, they scrutinize the abuse, violence and exploitations

³⁸ This is a type of communitarian ethics that enforce communal values on people without provision for democratic dialogue. This type of communitarianism does not encourage shared decision making and gender equality. I discuss this further under communitarianism above, under section 4.3.1.1, p. 68

that might follow and discuss what lessons can be drawn. It is important to realize that pure altruism, strong devotion and self-denial are virtues associated with care and throughout history have been praised as female virtues. According to Emmerich, altruism in its extreme form however is problematic, as it undermines autonomy, integrity and growth of both the carer and the cared-for (Emmerich, 2013).

I surmise that the model of care ethics provides another ethical template for analysis of ethical dilemmas different from the fundamental deontology or utilitarianism approach. The core of care ethics is two-folds: first is universal condemnation of exploitation and harm, and second is universal commitment to human flourishing. These two shared similarities with principle of non-maleficence and beneficence respectively but there are important differences. Whereas the principle of non-maleficence emphasizes refraining from harm, the care ethics in addition calls for prevention of harm actively. I opine that communitarianism and feminism differ from ethics of care, though they all appear complementary. For example, ethics of care has its distinct moral ontology and epistemology whereas communitarianism and feminism have a relatively shared ontological and epistemological foundation. The moral ontology is associated with the moral agent who is related, interconnected, mutually dependent and unequal in power and resources, while moral epistemology is based on not merely deduction and reasoning or rational calculations but on experiences, through exercising self-reflections and sensitive judgments where contextual differences are taken to account (Emmerich, 2013; Pols, 2015) . In this regard, I surmise that its philosophical foundation share similarities with communitarianism, but ethics of care strongly emphasizes experiences and relationships. This focus also distinguishes it from feminist ethics.

In the research scenario, I suppose that the care ethics appeal to the capacity of researchers to care for the study participants or communities, seeing them from the point of

dependency and vulnerability, and as mutually interconnected with them. The research participants are viewed as also caring for the researcher in offering their consent to participate. This bi-directional care paradigm activates a common experience, which impels these 'research actors' to change from narrow self-centeredness to caring for the well-being of one another. Hence such a scenario tends to make the experience and knowledge of care universal: everyone knows what care feels like, on the receiving end and as a giver of care. Subsequently, in event of a dilemma or conflict during the conduct of research, care ethics deal with it by appealing to rational identification, empathy, dialogues, re-conceptualization and imaginations.

4.3.5 Conclusion

In this section, I have discussed the relevant ethical theories applicable to my research, deliberated on their core values and relevance to the research scenarios. Though the epistemologies underpinning these theories differ, I opine that they are complementary in their applications to explaining moral behaviour and resolving ethical dilemmas, and therefore are relevant in the normative analysis of my research findings. In the next section, I discuss and compare ethical ideologies of liberal individualism and communitarianism which contribute to the discussion of my findings on decision-making and informed consent in genomic research.

Section two

4.4 Liberal individualism, Autonomy and Communitarianism

This section addresses the concepts of liberal individualism and autonomy and then compares them with communitarianism, critiques of them, and an attempt to provide a possible resolution of the diversity of opinions on liberalism and communitarianism as it applies to research participation and health care services. The understanding of the concept of autonomy,

which is the cornerstone of liberal individualism, is important to appreciating its antithesis to communitarianism which has been described as typical of sub-Saharan African communities (Andoh, 2011; Jegede, 2009), therefore I referred to these concepts in the discussion of my findings. At this juncture, it will be pertinent to offer further clarifications of these concepts by defining them.

4.4.1 Definition of liberal individualism

Though it is an herculean task attempting to define liberal individualism (Simon, 1999), liberalism can be conceptualized as a philosophy that emphasizes universal citizenship in that it encourages atomistic approach to decision making. Liberalism is expressed in terms of its core values, which include freedom, rights, equality, pluralism and distributive justice. These values are appealing because they empower individuals to live autonomously. This conforms with the goal of liberalism, which is to ‘create and maintain political institutions that foster these values, and through them, sustain autonomy’ (Keke, 1997: p 4). Personal or individual autonomy is defined as the voluntarism accompanying the right bearing quality of personhood.

The principle of autonomy is understood in a Kantian sense to mean that persons with rational capacity be permitted and encouraged to exercise that capacity, that is make choices and act according to their beliefs and values, and their capacity to do so should be nurtured and protected (Kant, 1964 [1758], p.114). In effect, it is the capacity for rational agency that constitutes the autonomy of rational beings as opposed to non-rational beings whose choices are based on natural necessity. In addition to principle of autonomy, Kant also proposed the ‘principle of humanity’ which refers to ‘acting in a way that you always treat humanity, whether in your own person or in the other person, never simply as a means, but always at the same time as an end’ (p.96), so people are not to be used solely for the purposes of others but treated with

respect and dignity³⁹ (Callan, 1997). According to Kant, decision must be based on reason alone, but there is evidence to show the effect of emotion on rational decision making (Gilligan, 1982; Nussbaum, 1990; Carse, 1991; Held, 1993). From my viewpoint, rational decision cannot be based on reason alone and this has been stressed by other authors including Walter *et al* and Callahan that the conception of rationality may be influenced by the emotional state of the individual, thus challenges self-determination (Callahan, 2003; Walter & Ross, 2014). This is further discussed under the critique of liberalism.

4.4.2 Concept of autonomy/liberal individualism

Epistemologically, liberalism has been viewed as a philosophical theory, which is explained first as a political theory founded on the natural goodness of humans and the autonomy of the individual, and favouring civil and political liberties, government by law with the consent of the governed, and protection from arbitrary authority, and second as an economic theory that favours laissez-faire economy, the free market, and the gold standard. This implies that as a political and social philosophy, it advocates individual freedom, representational forms of government, progress and reform, and protection of civil liberties.

According to Brennan, liberalism can be seen as a balance between two commitments; namely, commitments to liberty and to equality (Douard, 1993). The commitment to liberty is grounded in the impartiality of the liberal state toward the different conceptions of the good held by different individuals and by its willingness to allow different persons to pursue these conceptions with little interference. The commitment to equality is grounded in the regulative principle of treating everyone with equal respect and concern; given the inequalities of skills and

³⁹ This principle shares similarity with deontology which I discussed in section one – research participants are not ‘means to an end’

birth-rights of individuals (Brody, 1993; Menzel, 1992). Liberalism also emphasizes commitment to neutrality, and stresses tolerance of different citizens pursuing their different conceptions of the good life (Burtonwood, 1998).

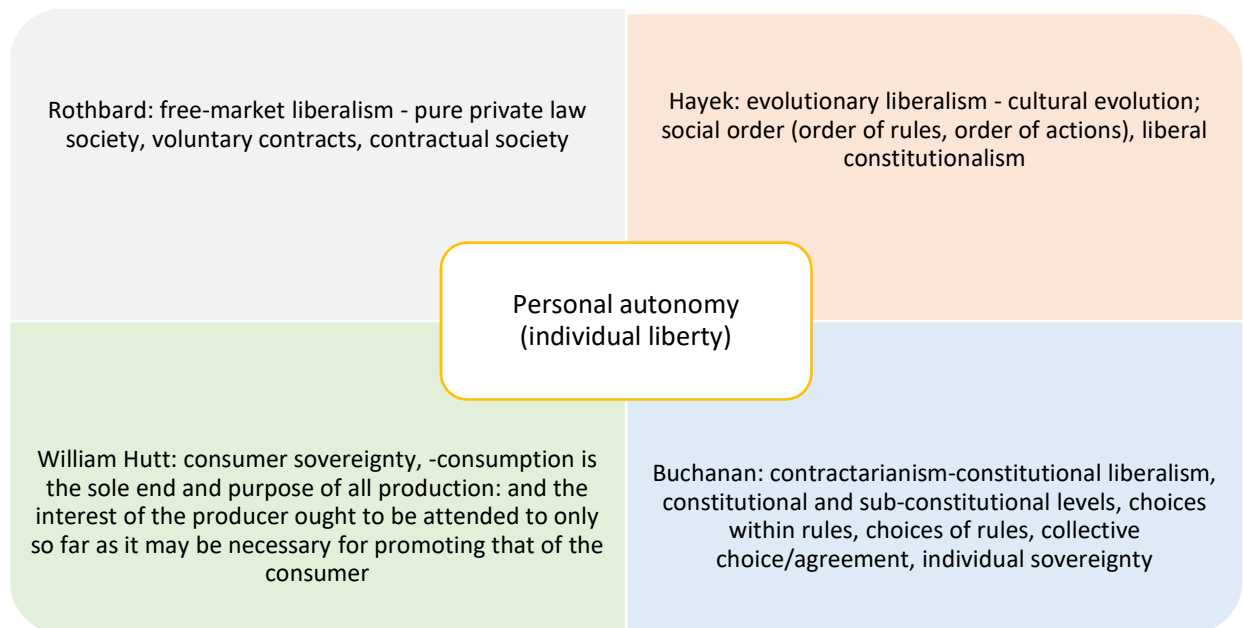
Within moral philosophy however, autonomy has two elements; the substantive and the procedural. The substantive defines autonomy in terms of the content of the agent's desires, values, or social situations while the procedural insists that autonomy remains content-neutral. According to Critch and colleagues, the procedural should be favoured above the substantive because of the perfectionistic tendency of the latter (Critch, Ridge, & Chrisman, 2010). This is to ensure that the account of autonomy that is offered within moral psychology is appropriate to the role autonomy plays in a political theory.

Mackenzie and Stoljar appealed to a feminist intuition⁴⁰ by explaining liberalism in the context of interference with personal deliberation and determination when they claimed that when women make decisions on the basis of internalised patriarchal norms, those decisions are not autonomous (Mackenzie & Stoljar, 2000). They stressed that an agent cannot be autonomous if they are embedded in relationships of subservience. In other words, if an individual has relinquished control over key decisions that affect their life, then they are non-autonomous irrespective of the internal structure of their motivational state. In effect, the feministic views claimed that autonomy can only be expressed in the setting of non-interference with the voluntariness of the individual. In my view, this implies that if the background conditions that an individual brings to a research experience, such as the institutional power relationships (for example, employer-employee or professor-student) and social contexts that influence their

⁴⁰ This is in consonance with feminist ethics discussed earlier in section 4.4.2, p.86

options cannot be ignored, then autonomy is relational. Thus, an individual's identity is 'formed within the context of social relationships and shaped by a complex of intersecting social determinants, such as race, class, gender, and ethnicity' (Mackenzie & Stoljar, 2000), and also sexual orientation. This is relevant in focus groups or interviews involving female research participants. As much as possible, a researcher must provide or create an atmosphere that encourages free expression of opinions without intimidation. In practical terms, male and female focus group participants should be separated into different groups to achieve free expression of opinions.

Notwithstanding, all classical liberal tradition shares a common core - individual liberty - as the fundamental principle of a desirable social order. So liberal concepts are based on normative individualism in that evaluations of the individuals themselves are the only source from which legitimacy in social matters can ultimately be derived (Burtonwood, 1998). Despite the positive values and the significance of autonomy to liberalism as a moral philosophy, there exist disagreements among the proponents of liberal individualism on how better to apply the core value of autonomy to the individuals' rights and how these rights affect others within the same community. These disagreements resulted in attempts to re-define liberalism using various philosophical discourses which need mentioning to enhance our understanding of the scope of liberalism. These attempts shared the fundamental core value of personal autonomy or individual liberty, as depicted in Figure 2, but used different frameworks to stress the importance of individual sovereignty thereby defending personal liberty. These frameworks include: contractarian-constitutionalism (Buchanan, 1989; Vanberg, 2014); free market liberalism (Rothbard, 1998); evolutionary liberalism (Hayek, 2004); and consumer sovereignty model of liberalism (Hutt, 1940).



(Source: Author) Figure 2 – Different paradigms of liberal individualism - (Personal autonomy is central to all paradigms)

4.4.3 Contributions to health research

An obvious application of the liberal philosophy is in medical ethics. The moral analysis of the researcher-participant interaction has been permeated by two dogmas, first the assumption that research participants have a ready-made and fixed capacity to act autonomously, provided they receive the information necessary to do so, and second is the assurance of non-interference from the researchers as research participants exercise this capacity (Brody, 1993; Chou, Kellom, & Shea, 2014).

In the setting of health research, the meaning of autonomy focuses on the concept of self-governance. Therefore, autonomous behaviour has two key elements. First, it is behaviour that is governed by plans of action formulated through deliberation, which involves investigation of the factual circumstances affecting the choice of goals and the means for achieving them as well as the setting of preferences based upon such investigation. Second, autonomous behaviour involves

self-rule implying that it is intentional and voluntary, based upon choices persons make deriving from their own life plans. In health sector it is taken that once the informational inequality resulting from the highly technical nature of medical knowledge is resolved, then the decision making process becomes autonomous (Brody, 1993; Douard, 1993). But this is not always the case. This can be illustrated using informed consent. Despite the fact that the individual's possession of adequate information is crucial for intelligent choice either in research or medical care (Chima, 2013), autonomous choice is affected by interplay of other factors such as language difficulties, lack of interpreters, time constraints, communication skill of the researcher and level of education of participants. In a case-controlled study that investigated voluntary participation and comprehension of informed consent among women involved in a genetic epidemiological study on breast cancer, the investigators showed that 68% of the cancer patients and 47% of the controls recalled being told of the risks associated with participation (Marshall et al., 2014), implying that some of the research participants lack understanding of the risks involved in the research. Overall, it is the responsibility of the researcher to ensure that research participants possess sufficient knowledge of the research before consenting (Sugarman & Paasche-Orlow, 2006).

The drawback to autonomy, especially in the context of therapeutic medicine, is that the potential impact of illness on the capacity of individuals to exercise autonomy is ignored. Equally powerful in their impact upon autonomous functioning are the operation of affective factors which accompany the disequilibrium that illness imposes upon the interaction of persons with their environment. These psychological components include anxiety, anger, depression, denial and guilt. These factors may prevent assessment of the facts and thorough evaluation of options available for revised activities. These factors can impede the attempt to act upon coping

strategies, thus impinging significantly upon deliberative and operational dimensions of autonomous behaviour.

4.4.4 Critique of liberal individualism

Despite the attractiveness of the liberal autonomy philosophy and its significance in shaping ethical foundations of health care and research, the complexity of human interactions and evolution of our values exposed the inadequacies of liberalism. Of all these shortcomings, the main drawback to the Kantian philosophical stance of liberalism is the inability of application of autonomy to those who lack capacity for rational agency. The capacity for autonomy is an inherent potential, it is either present or absent, whereas ability is the immediate possibility to demonstrate autonomy. However a person may be capable and able but fail to exercise autonomy for one reason or the other (Killmister, 2013).

Many theorists have now accepted that autonomy is primarily a local rather than a global phenomenon. It is quite possible to be fully autonomous with respect to one sphere of activity or preferences, and less autonomous or even non-autonomous in another. If there is capacity for an activity, and that activity is central to human life, then as a society we have an obligation to ensure that the social conditions for the exercise of that capacity are provided. Of all the spheres of human life, our practical agency is certainly amongst the more central. Therefore recognition of obstacles to an agent's ability to exercise her autonomy brings with it a reason to remove those obstacles, provided the agent has the necessary capacities (Killmister, 2013).

Also, the principle of liberty places a justifiable restriction on autonomy. John Stuart Mill, on the principle of liberty, stated that the choices of those possessing rational agency need not be respected when the resulting actions pose a risk of harm or actually cause harm to others or to the

society (Misra, 2012). This implies that the choices of rational beings are unacceptable if others are at risk of harm as a result of their choices.

One of the assumptions of liberalism that has been criticised is that of morality. The liberal faith assumes that human nature is basically good. Rawls in a passage from '*A Theory of Justice*', stressed that simply enhancing autonomy will not reduce the prevalence of evil but that people who grow up in a just society and are exposed early to just and fair practices will acquire a disposition to support just practices and institutions (Rawls, 1979). So, the emphasis on the moral person implies that propensity for injustice by people is not a permanent aspect of community life but it is greater or less depending largely on social institutions, and in particular on whether they are just or unjust. This demonstrates the communitarian contribution to prevention of societal evil (Beggs, 2009). Owens and Cribb (2013) criticized individual autonomy by emphasizing the social and structural influences on individuals' capacity to exercise autonomous agency (Owens & Cribb, 2013). Similarly, Daniel Goldberg (2012) criticized 'methodological individualism' in health promotion because it is ineffective, increases health inequalities and enhances stigmatization. The proponents of communitarianism remain the major critics of liberal individualism. In the next section, I compare these two ethical concepts.

4.4.5. Comparing Communitarianism and Liberal individualism

Communitarianism remains the outstanding critic to liberal individualism, emphasizing the importance that the common bonds between people are necessary for both their psychological well-being and their self-actualization. Because communitarianism focuses more on common good and solidarity, the issue of classical liberal autonomy does not hold in communitarian ethics. It may however be modified to provide a meeting point for the two philosophies. This was

the stance of liberal or responsive communitarianism and modern liberalism or relational liberalism. This is a move for a conceptual repositioning of autonomy as capacity of rational individuals to make informed un-coerced decisions without, at the same time and in the same regard, abrogating their obligations and responsibilities to other people (including future generations) as well as the particular conditions of society at a given time. This ensures that individuals do not lose their self-determination capacity while submitting to a mutually acceptable socio-political institution put in place by all citizens for the common interests of all.

Consequently, communitarianism has become an acceptable alternative to liberal individualism among some bioethicists because of its overlap with utilitarianism⁴¹ and focus on individuals being ‘situated agents’ meaning that people are neither fully free nor fully constrained. In other words, individuals have great potential for self-determination and moral autonomy but are nevertheless conceived as highly socialised and deeply influenced by the values, beliefs, practices, and opportunities handed to them by their communities (Etzioni, 2006; Karp, 2000). Communitarianism affirms that individuals are socially construed implying that personhood is woven into communality and people find meaning in life by interpreting their actions and values within the framework of societal norms and culture. In other words, one is a self only among other selves. A self can never be described without reference to those who surround them. The communitarian requirement that persons be socially constituted means that our very being as persons is derived from the existence of our community. So, our personhood is dependent on community and we cannot be persons without community. In the absence of community, we lose our essential nature as persons.

⁴¹ Utilitarianism, also referred to as ‘Consequentialism’, emphasises the outcomes or consequences of an act rather than the act itself. The basic utilitarian premise is that our actions should maximise utility which is normally defined in terms of happiness for the greatest number of persons affected by an action, the concept of the greater good.

Though communitarianism requires social institution, it also requires the independence of the individuals from the community i.e. the ability of individuals to remain persons without any social structures and a corresponding ability to choose voluntarily without the influence of the community. Cohen critiques communitarianism by examining the interpretation of autonomy from the communitarians' point of view and the description of personhood in the context of the society that communitarianism seeks to create (Cohen, 2000). He concluded that the existence of a liberal individual is a fact about our society since in reality there are individuals who claim not to share a desire for solidarity within the community implying that we either have a deep independent self which can make rational autonomous decisions or willingly relegate our individual choice to promote the collective choice of the community. I opine that Cohen's view suggested an interdependency between liberal individualism and communitarianism in that individuals' choice to engage in communal practices and demonstrate solidarity is autonomous thereby stressing the role of self-determination towards achieving the values of communitarianism.

4.4.6 Conclusion

Despite criticisms of liberal individualism, it has contributed significantly to development and advancement of health-related innovations especially research. It has focused attention on the need to avoid paternalism, exploitation, tyranny and subjugation by promoting liberty, rights and autonomy. It is clear ethical issues cannot be solved by applying the theories of liberalism alone. The challenge therefore is to adopt a middle course that embraces a consensus between autonomy and communitarianism, accepting that autonomy is not purely individualistic and without the influence of the family, community, shared history of traditions, and without regard to shared values or interests of the community. We have to accept that individuals are socially construed,

and personhood is woven into communality, finding meaning in life by interpreting individual's actions and values within the framework of societal norms and culture, which evolved and are designed by the individuals themselves through deliberative choices and actions. For as long as the foundation of societal norms rest on individuals' choices and their deliberative actions in accepting to live without coercion within the community with others, then individual's autonomy becomes 'relational autonomy'⁴². It is in the understanding of this concept of 'relational autonomy' that a meeting point may be established.

In this chapter, I have discussed the ethical principles and theories which will serve as the basis for my ethical reasoning and integrating my data with these theories to arrive at normative conclusions. In the next chapter, I deliberate on the theoretical foundation and development of bioethics in sub-Saharan Africa, review the existing ethical guidelines in Europe, and compare them with the Nigerian National Code of Health Research Ethics with the objective of identifying the deficiencies in ethical framework of guidelines in sub-Saharan Africa using the Nigerian Code as an illustration. Subsequently, I highlight the gaps in the existing sub-Saharan ethical guidelines that my thesis aims to address.

⁴² Wardrope Alistair (2015), Walter, J and Ross, LJ (2014) and Mackenzie, C and Stoljar, N (2000) advocated moving beyond the limits of isolated individualism by highlighting the relevance of relational autonomy. Relational autonomy is the social context within which all individuals exist and acknowledge the emotional and embodied aspects of decision making. It acknowledges the central role of social structures like communal and interpersonal interactions in decision-making without relegating the intentions and goals of individuals.

CHAPTER 5

Bioethics in Sub-Saharan Africa

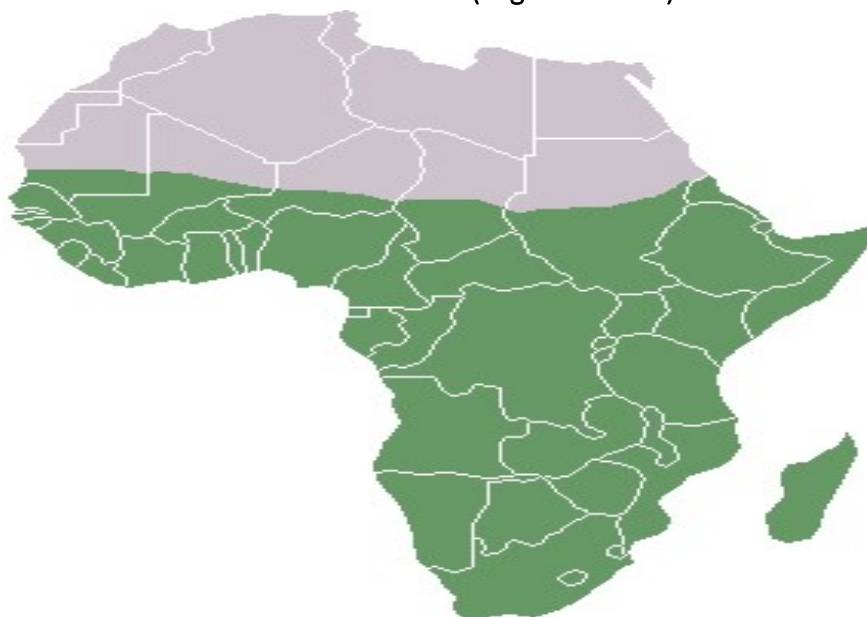
5.1 Introduction

Sub-Saharan Africa is the geographic region that includes all the African countries immediately below the Sahara Desert, together with all the associated island states (Highbeam Research, 2004) - see Figure 3. In addition to a multitude of indigenous languages, most of the countries are either Anglophone or Francophone, five are Lusophone (Portuguese-speaking). These countries are developing economies characterized by poor resource availability, lack of expert capacity and user-friendly information management systems to support the flow of research proposals through independent ethics review process (Sun, 2013).

The history of medical ethics in sub-Saharan Africa cannot be considered to be homogenous because this vast geographic area contains 50 independent countries with innumerable socio-cultural groupings (Highbeam Research, 2004). Many of these countries are nation states only superficially, since their borders enclose ethnic groups that have little in common with their fellow citizens, being more closely affiliated with groups in other countries. Also, some of the countries have had contact with scientifically based European medicine for less than 50 years, and others for more than 100 years (Highbeam Research, 2004) further contributing to the heterogeneity of these countries, diversities of health care infrastructure and disparities in capacity for medical research.

According to the Encyclopaedia of Bioethics (2004), it might appear that “the development of medical ethics in all these countries tended to follow the existing European ethical values, principally those of France and Great Britain, the two dominant colonial powers.

Figure 3. The sub-Saharan African countries (in green colour)



The sub-Saharan

African countries include:

- | | | | |
|------------------------------------|-----------------------|------------------------------|--------------------|
| 1. Angola | 13. Côte d'Ivoire | 26. Madagascar | 39. Seychelles |
| 2. Benin | 14. Djibouti | 27. Malawi | 40. Sierra Leone |
| 3. Botswana | 15. Equatorial Guinea | 28. Mali | 41. Somalia |
| 4. Burkina Faso | 16. Eritrea | 29. Mauritania | 42. South Africa |
| 5. Burundi | 17. Ethiopia | 30. Mauritius | 43. Sudan |
| 6. Cameroon | 18. Gabon | 31. Mozambique | 44. Swaziland |
| 7. Cape Verde | 19. The Gambia | 32. Namibia | 45. Tanzania |
| 8. Central African Republic | 20. Ghana | 33. Niger | 46. Togo |
| 9. Chad | 21. Guinea | 34. Nigeria | 47. Uganda |
| 10. Comoros | 22. Guinea-Bissau | 35. Réunion | 48. Western Sahara |
| 11. Congo (Brazzaville) | 23. Kenya | 36. Rwanda | 49. Zambia |
| 12. Congo (Democratic Republic) | 24. Lesotho | 37. Sao Tome and Principe | 50. Zimbabwe |
| | 25. Liberia | 38. Senegal | |

5.2 Historical perspective

It is believed that pre-colonial African nations have their own indigenous acceptable moral values, but the concept of contemporary medical ethics was probably introduced to Africa by the colonial medical practitioners (Tosam, 2014; Udokang, 2014). These European medical professionals, faced with traditional African medical practices took the position that all such medical practices and values, as well as their practitioners, were crude and uncivilized. Traditional African healers were considered no more than quacks and deceivers and therefore were either ignored or actively persecuted (Highbeam Research, 2004). To a certain extent such attitudes were likely based on the colonialists' Christian values, since much of traditional healing relied on the intervention of gods and spirits, which Christians found abhorrent, so the practice of traditional healing was strongly discouraged (Agulanna, 2008).

The field of bioethics is not progressing or flourishing on the African continent as in other parts of the world but in the last one or two decades there appears to be an increasing awareness of an urgent need for ethical regulation of research in sub-Saharan African countries. This increased awareness, I propose, may be due to two reasons; first the series of public revelations of gross abuses of human participants who had been coerced into participation in research, and second the increasing numbers of collaborative multi-national clinical trials' sites in sub-Saharan Africa that require ethical oversight from local authorities.

To discuss the first reason, I present some of the unethical studies conducted in sub-Saharan Africa which have been reported to buttress this. For example, the Development of Antiretroviral Therapy in Africa (DART) trials conducted in Uganda, Zimbabwe and Cote d'Ivoire between 2003 and 2006, was an open, randomised study to compare standard continuous therapy (SCT) with structured treatment interruption (STI) of 12 weeks on and 12 weeks off anti-

retroviral therapy. Unfortunately, the investigators did not comply with the Data and Safety Monitoring Board's demand to stop the study and some of the patients died during the interruption period (Camp et al., 2005). The conduct of the investigators contradicts fundamental ethical guideline of halting a study when the risks outweigh the potential benefits (World Medical Association, 2008).

In South Africa, azidothymidine (AZT) regime was used to investigate the potential to reduce the mother-to-child transmission of HIV in South Africa without the investigators providing for the best-proven therapeutic method (gold standard of therapy) as the control but used a placebo control arm (Lurie and Wolfe, 1997) despite the fact that zidovudine has been proven to reduce maternal-infant transmission of HIV five years earlier (Connor et al., 1994). This contradicts the ethical standard of care (World Medical Association, 2008). In Nigeria, the Pfizer drug trial of Trovan among the patients with meningitis during the epidemic outbreak in Kano turned into a scandal as the patients' relations were not informed and proper informed consent process was not followed. Though the investigators claimed that ethical approval was obtained in Nigeria, it was not clear if the protocol was reviewed by a properly constituted ethics committee (Ready, 2001). This spate of unethical conduct of clinical trials resulted in the ethical deliberations on issues of rights of patients, protection of human subjects and their autonomy in the African continent. Consequently, ethical codes were developed in response to a problem, crisis or revelation of research abuse in seven of these sub-Saharan African countries, namely South Africa, Nigeria, Cameroon, Kenya, Uganda, Botswana and Zimbabwe.

On the second reason, sub-Saharan Africa is increasingly being used as a site for clinical trials (Andanda et al., 2011; Gordijn, 2014). Internationalization is no longer a recent phenomenon in research and this has made health research a global issue without national

frontiers (Benatar & Singer, 2000). Research on human participants continues to increase in resource-poor sub-Saharan countries, especially as collaborations between foreign and local researchers become popular. This new trend of multi-national research has resulted in increasing numbers of collaborative international studies that required competent ethical review of research protocols and oversight functions by local ethics committees and acceptable institutional capacity for ethical conduct of research. This demands that researchers are knowledgeable in research ethics, and that there are ethics committees capable of independent review of research protocols and oversight functions. Unfortunately, the existing evidence shows the lack of experience in application of ethical principles among researchers (Taiwo & Kass, 2009), and lack of ethical review of protocols in sub-Saharan African countries. This has been attributed to the weak capacity for ethical responsibilities in research institutions (Hyder et al., 2004; Ogundiran, 2004; Ogundiran & Adebamowo, 2010).

Therefore, there is a need for agreement on the basic values that govern medical research so that same standards apply to human subjects participating in the same research in different countries otherwise countries that do not enforce high ethical standards or without an existing ethical framework may be exploited especially if the benefit will go primarily to other populations rather than the trial population (Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries, 2002). Furthermore, medical research is now a major investment for private industry. Economic gains are anticipated, as a result the strong drive to make health research an engine of economic development runs the risk of pushing research beyond acceptable ethical standards (Angell, 1997). With the increasing research activity going on in sub-Saharan Africa, one would expect that research ethics would also be gaining ground within the region (Gordijn, 2014) but this is not so. The poor ethics capacity also contributes to

the lack of ethics review committees which have been reported in most of the African countries by Kirigia, Wambebe and Baba-Moussa (Kirigia, Wambebe, & Baba-Moussa, 2005). Also, the World Health Organisation (WHO) Regional Committee for Africa, in 1998, passed a resolution (AFR/RC48/R4) which urged its Member States in the Region to develop national research policies and strategies and to build national health research capacities, especially legal systems that enhance ethical practices (World Health Organization, 1998). To better appreciate the landscape of bioethics development in the sub-African setting, I discuss ethical regulation in the sub-region.

5.3 Ethical regulation in Africa

Traditionally it is believed that bioethics is associated with cutting edge biotechnologies such as in vitro fertilization, organ transplant and gene therapy which are virtually non-existent in most parts of Africa. These technologies contributed to exponential growth of bioethics in North America and Europe, and stimulated deliberations which gave birth to regional and inter-regional ethical guidelines such as Council of Europe and Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 1994 (Council of Europe, 1994). Among other core ethical issues, this guideline addressed embryo research by emphasising that in vitro research on embryo shall ensure protection of same and creation of embryo for research purpose is unacceptable (Council of Europe, 1994).

However, the principles of bioethics which were formulated to address ethical issues arising from these medical advances were thought not to be applicable to Africa and cannot adequately equip African researchers with the necessary ethical skills to face the bioethical dilemmas that they encounter daily (Andoh, 2011). The ethical issues, approaches and values were seen as a Western phenomenon or western-dominated ethical advancement (Ogundiran,

2004). As plausible as this may appear, I surmise that African researchers regrettably failed to perceive the similarities between the simple medical procedures they routinely perform, such as blood transfusion and umbilical cord genotyping, and the advanced technologies including heart transplant and embryo cloning. The lack of recognition that the ethical principles and values which apply to heart transplantation, with minor differences, also apply to blood transfusion (since the latter is a form of transplant procedure) resulted in their failure to be pro-active. The emergence of these novel technologies should have served as motivation for African researchers to participate in the dialogue and develop their ethical capacity, especially with the realization that these medical advances will eventually be introduced to Africa as exemplified by genomic research and the H3 Africa project.

Furthermore, despite the importance of application of ethics to research, there has been little or nothing done by African governments and academics to develop capacity for the discipline in sub-Saharan Africa until recently when a few countries namely South Africa, Kenya, Uganda, Tanzania, Nigeria and Ghana formulated ethical guidelines for health research. Some authors felt that this was either due to lack of inadequate funding arising from no budgetary allocations or financing of research in the area of bioethics, or lack of political will and commitments from African governments as politicians are not interested in this kind of research. As a result, African governments have not yet established the necessary legislation, institutions or infrastructures to protect vulnerable persons and to address bioethical issues (Andoh, 2011; Zielinski et al., 2014).

I opine that, as much as these observations might have contributed to the slow development of ethical regulations in SSA, the lack of awareness of significance of ethical governance of research among African researchers and weak infrastructural support for socially

valuable and community-oriented research are more pertinent factors. A Nigerian study showed that only 37.6% of 133 health researchers had adequate knowledge of criteria for ethical regulation of research (Adeleye & Ogundiran, 2013). Emanuel *et al* stated in their paper that ‘the social value of research for the host community must be explicitly specified and enhanced’ for its importance to be appreciated (Emanuel, Wendler, Killen, & Grady, 2004: p3). For example, malaria is a substantially greater health problem for most countries in SSA than for developed countries of Europe, hence improvements in interventions for cerebral malaria may be of substantial value to people of SSA whereas research on myocardial infarction will be more valuable to Europeans. Therefore, a research on myocardial infarction is less likely to be valued by policy makers in sub-Saharan Africa. These factors, I believe, might have contributed to inappropriate health policies and planning including poor research governance and development in sub-Saharan Africa.

Now the ethical regulation of research in sub-Saharan Africa requires urgent attention and intervention because ethical and legal challenges encountered in research are difficult to resolve in the absence of sound regulatory frameworks. Encouragingly, the field of bioethics has in the last decade witnessed advances in some African countries, with centres of bioethics found in countries like South Africa, Nigeria, Kenya, Tanzania, Democratic Republic of Congo and Botswana, and hopefully other countries are expected to follow these examples. Though bioethics in Africa is poorly funded, narrowly focused and lacks unified philosophical framework, bioethics education and training is experiencing some growth and transformation partly due to contributions of some African scholars who have undergone some training in Western institutions and partly due to partnerships and collaborative networks and funding from Western agencies

including National Institute of Health and Fogarty Institute in the United States (Ndebele et al., 2014; Ouwe-missi-oukem-boyer, Syntia, Ntoumi, & Nyika, 2013).

There are no academic institutions that provide formal training in research ethics in most of the countries in sub-Saharan Africa with exception of South Africa, Malawi and Nigeria (Ndebele et al., 2014). In Cameroon, for example, the majority of researchers and members of RECs have to rely on web-based courses or workshops and seminars to obtain training in research ethics (Gordijn, 2014; Ouwe-missi-oukem-boyer et al., 2013). Initiatives to organize training are often taken by non-governmental organisations with very little funding, or funding from external international organisations. There have been various bodies within and outside Africa that pioneered the movement towards ensuring that medical research in sub-Saharan Africa conforms to international ethical guidelines. This was anchored by the Pan African Bioethics Initiative (PABIN), a pan-African organisation established in 2001 to foster the development of bioethics in Africa with a particular focus on research ethics (Ogundiran, 2004).

5.4 Regional and National ethical guidelines in sub-Saharan Africa

There are very few sub-Saharan African countries with any ethical regulatory framework for research. A study that reviewed five sub-Saharan African countries for national regulatory authorities overseeing research and informing the right to informed consent revealed diverse frameworks for different countries with legal frameworks to regulate research but weak ethical structure to resolve ethical dilemmas (Andanda et al., 2011). This scenario is unfavourable because every country or institution involved in the conduct of research, including research involving human participants, should have adequate capacity to conduct expert and efficient ethical review of such research, as this will promote better health, equity and development

outcomes. This is particularly important now because of the increasing complexities of research for example the emergence of the genomics research industry.

Another study that described the state of research ethics policies and practices in health institutions in 42 sub-Saharan African countries using a structured questionnaire revealed that 51% reported having policies on research ethics and 58% had written policies requiring that researchers obtain informed consent of research participants. But only 34% (one third) of health institutions had established ethics review committees, with 42% requiring that protocols must be reviewed, and 46% had linkages with national or regional ethics organisations. Less than 25% had policies in place for oversight functions, with 34% of these requiring annual ethical review. Only 36% provided any type of ethics training for staff including those conducting health research and those who were not members of the REC (Zielinski et al., 2014). This further supports the need for capacity building in order to ensure the protection of safety, rights and welfare of study participants and of the communities that host research. This was corroborated by another study (Kirigia & Wambebe, 2006).

Hyder *et al* reported that in developing countries of Africa, Asia and South America, 44% of survey respondents did not submit their studies for any type of review whether ethical, technical or scientific, by the ministry of health in the developing country where their research was carried out (Hyder et al., 2004). Advancing a different position, a publication stated that there is currently over 173 ethics committees known to be operating in 37 African countries with great variability in skills, membership, resources and capacity (Sun, 2013), this report is inconsistent with majority of published data originating from the sub-Saharan African countries. It is possible that some other regulatory bodies such as national ministries of health and regional ad hoc bodies advocating ethical conduct of research were erroneously labelled as ethics

committees. In the next section, I present a comparative analysis of six European (including three UK) ethical guidelines and the Nigerian Code of Health Research Ethics (NCHRE). The European guidelines are selected based on ease of availability and relevance to biomedical research.

5.5 Comparative analysis of UK and European Ethical Guidelines and the Nigerian National Code of Health Research Ethics

In this section, I give an overview of the Nigerian Code. I also compare the Code with seven European ethical guidelines comprising the a) the UK Research Integrity Office's Code of Practice for Research (UKRIO-CPR); b) NHS Health Research Authority's Policy framework for Health and Social Care Research (NHS-HRA framework); c) Nuffield Council on Bioethics Report – three UK-based guidelines; and d) Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Council of Europe); e) Directive 2001/20/EC (good clinical practice in the conduct of clinical trials on medicinal products for human use); and f) Opinion of European Group on Ethics in Science and New Technologies to the European Commission on Ethical Aspects of Clinical Research in Developing Countries.

5.5.1 Nigerian National Code of Health Research Ethics

The need for adaptation of basic ethical principles to diverse cultural settings and societal norms within the framework of global ethics has stimulated the development of national and regional ethical codes that will meet the peculiar challenges in human subject research and provide solutions to potential ethical dilemmas in these societies. This is particularly relevant to developing countries where guidelines need to be 'culturalized' (Federal Ministry of Health, 2007). The National Code of Health Research Ethics (NCHRE) addresses most ethical issues relating to research with human participants but does not address standard of care, embryo and

genomic research although it stipulates guidelines for material transfer agreement⁴³ (Federal Ministry of Health, 2007).

5.5.2 The United Kingdom Research Integrity Office Code of Practice for Research

The UK Research Integrity Office's Code of Practice for Research was designed to encourage good conduct in research and help prevent misconduct, in order to assist organisations and researchers to conduct research of the highest quality (UK Research Integrity Office, 2009). It complements existing and forthcoming guidance on research conduct such as that provided by the Research Councils UK, Wellcome Trust or the Council for Science and Technology. The Code emphasises the following goals: Excellence in research, Honesty, Integrity, Cooperation, Accountability, Training and Skills and Safety. The Code states general ethical principles and outlines the responsibilities for researchers and organisations. The principles to be observed when conducting research involving human participants, human material or personal data include compliance with all legal and ethical requirements not only in the UK but also in countries where research is conducted, primary recognition of dignity, safety and rights of participants, ensure confidentiality and security of personal data relating to human participants in research and human material in research (of particular relevance to genomic research), regulatory and peer review and approval of research projects, appropriate mechanisms to obtain informed consent, duty to communicate research findings, identification and reporting of risk or harm to research participants, or improper or unlicensed use or storage of human material or data.

⁴³ See section 1.1, p.4

5.5.3 NHS Health Research Authority UK Policy Framework for Health and Social Care Research (NHS-HRA framework)

The NHS Health Research Authority framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research in the UK. The main objectives of this framework are to protect and promote the interests of patients, service users and the public by describing ethical conduct and thus supporting and facilitating high-quality research. the framework applies to all organisations and individuals with responsibilities for health and social care research, including funders, sponsors, researchers and their employers, research sites and care providers (NHS Health Research Authority, 2017). This framework represents a compatible standard for research ethics applicable to England, Scotland, Northern Ireland and Wales. Within the context of genomic research, this framework promotes making data and tissue collected for research available for future analysis, with adequate consent and privacy (NHS Health Research Authority, 2017).

5.5.4 Nuffield Council on Bioethics – The ethics of research related to healthcare in developing countries

The Nuffield Council on Bioethics is jointly funded by the Medical Research Council, the Nuffield Foundation and the Wellcome Trust. The report of the Council on ethics of research related to healthcare in developing countries was published in April 2002. This guideline addresses the issues of informed consent, standard of care, post-trial access to benefits of research, ethical review of research projects and emphasises capacity building by recommending the development of local expertise in the provision of healthcare and healthcare research as an integral component of any proposed research. The guideline was based on fundamental ethical principles of respect for persons, justice and beneficence, but with a guiding framework on sensitivity to the cultural differences between developing and developed countries which may

affect ethical practice and procedures, and promote respect for persons, alleviate suffering, and prevent exploitation of the vulnerable populations (Nuffield Council on Bioethics, 2002).

5.5.5 Other European guidelines

The Council of Europe guideline was published in 1997, and the Directive 2001/20/EC in 2001. Both are concerned with good clinical practice as it is mainly applicable to interventional trials, demands that relevant member states of the EU must enter certain information in the European clinical trials database and ensure that principles of good manufacturing practice apply to investigational medicinal products. The Opinion of European Group on Ethics in Science and New Technologies to the European Commission was published in 2003.

5.5.6 Comparison of key ethical elements

This section compares the Nigerian Code with European guidelines including three UK ethical codes, in a tabular format, with emphasis on independent ethical review of protocols, composition and responsibilities of ethics committees, risk/benefit assessment, informed consent process, principle of distributive justice, data and safety monitoring, standard of care of control group, confidentiality, community engagement, protection of research participants, ethical dissemination of research results and genomic research. Details are summarized in Table 2.

5.6 Pitfalls and gaps in the Nigerian Code

Despite the extensive areas of ethical regulations covered by the Nigerian Code, there are sensitive areas that it does not address, some of which are particularly relevant to novel technologies in health care research. For example, it does not address peculiarities of engagement in genomic research which my research is designed to address. There is no information on what consent process is acceptable to potential research participants. And there are no ethical guidelines for bio-banking procedures, though the material transfer agreements cover export of

human biological specimens, but this is not comprehensive. Furthermore, the roles of the Community Advisory Board (CAB) needs expansion to include its role in effective engagement of communities in highly ethically sensitive research like genomics. There are other gaps in the Code. For example, there are no comprehensive guidelines or instructions for obtaining consent from vulnerable populations such as pregnant women, children, prisoners, and mentally ill individuals. The issues like organ transplantation, embryo transfer and in-vitro fertilization, and end-of-life ethical issues are not specifically addressed. Also, the ethical guidelines to guide conduct of research with new investigational devices is not addressed.

5.7 Conclusion

There are significant gaps in the Nigerian Code, especially the lack of ethical guidelines for conduct of genomic research. The need to fill these gaps is now more urgent as biobanks emerge in the country. I believe the findings of my study will serve as a template or framework for the development of such an ethical guideline. As a prelude to part two which addresses my methods, I discuss empirical research in bioethics in the next chapter since my research is an empirical, qualitative study. I highlight the shift in, and relevance of, empirical study to bioethics.

Table 2 Comparison of key ethical elements

| Ethical elements | Ethical guidelines | | | | | | |
|---|------------------------|----------------------|---------------------------------------|--------------------------------|-----------------------------|--|--|
| | UKRIO-CPR ^a | NHS-HRA ^b | Nuffield Council ^c | Council of Europe ^d | Directive 2001 ^f | Opinion of European group ^g | NCHRE ^h |
| <i>Independent review of protocols</i> | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| <i>Risk assessment</i> | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| <i>Informed consent</i> | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| <i>Justice</i> | Yes | Yes | Yes | Yes | No | Yes | Yes |
| <i>RECs composition and responsibilities</i> | Yes | Yes | No (mention in passing) | Yes | No (mention in passing) | No (mention in passing) | Yes |
| <i>Standard of care</i> | Yes | Yes | Yes | Yes | No | Yes | No |
| <i>Confidentiality</i> | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| <i>Dissemination of research findings</i> | Yes | Yes | Yes | Yes | Yes | Yes | Partially |
| <i>Community engagement</i> | No | No | Yes | No | No | No | Yes (emphasises the CAB ⁱ) |
| <i>Data and safety monitoring</i> | Yes | Yes | Yes | No | Yes | No | Yes |
| <i>Ethics education, consultation and clinics</i> | Yes | Yes | No (mention ethics capacity building) | No | No | No | Yes |
| <i>Protection of research participants</i> | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| <i>Genomic research</i> | Yes | Yes | No | Yes | Yes | Yes | No (except MTA ^j) |

Legends: ^aUnited Kingdom Research Integrity Office Code of Practice for Research; ^bNHS Health Research Authority UK Policy Framework for Health and Social Care Research; ^cNuffield Council on Bioethics – The ethics of research related to healthcare in developing countries; ^dCouncil of Europe; ^fDirective 2001/20/EC; ^gOpinion of European Group on Ethics in Science and New Technologies; ^hNigerian Code for Health Research Ethics; ⁱCommunity advisory board; ^jMaterial transfer agreement

CHAPTER 6

Empirical Research in Bioethics

In this chapter, I discuss empirical bioethics focusing on its definition and types, the ‘empirical turn’ in bioethics and the arguments for and against this development in bioethics research, the methods of integrating empirical and normative analysis in bioethics, and thereafter describe how my thesis is positioned within this theoretical framework. Furthermore, since my thesis is an empirical study I therefore, in this section deliberate on the advantages of empirical research to genomic research and healthcare in general, thereby justifying why I chose the empirical methods I used.

6.1 Introduction

Bioethics, as an academic discipline, has over the years focused on philosophical reasoning to arrive at normative conclusions when addressing ethical inquiries. This position has in recent times been criticised because of the lack of empirical context of normative statements emerging from theoretical, rational analysis carried out by the ethicists. This is because the observations from empirical research in bioethics are perceived to strengthen and validate ethical theories making them context-specific and socially relevant, and applicable to practice.

It is useful to discuss the reasons for the application of empirical methods to ethical inquiries because my thesis makes use of empirical data to answer practical ethical questions in genomic research with the goal of providing propositions on how to handle potential ethical dilemmas. This is vital as technological innovations and medical advancement influence how people act and, further people can also influence the way technologies are enacted. In the genomic research setting for example, the storage and export of human biological specimens affect how people accept genomic testing and this in turn affects bio-banking governance regulations and procedures.

In this context, empirical studies can therefore take the form of accompanying research following new developments like in genomics “such that ethical projects ‘run along’ with technical or medical-scientific research” (Pearlman, Miles, & Arnold, 1993: p 199). So instead of engaging only in theoretical reasoning and applications of existing ethical principles like autonomy, justice and beneficence to answering my research questions, I employed empirical qualitative research methods (interviews and focus group discussions) to show what variables or social factors become relevant, how they develop, what shape the interactions between humans and innovative technologies and how to interpret these relationships (Jacoby & Siminoff, 2008) within the context of consenting process and community engagement in genomic research.

6.2 Definition

Empirical ethics (EE) may be defined as the application of empirical research to resolving ethical dilemmas and inquiries (Hurst, 2010; McKeown, 2015). Several authors see it as a generic and broad term used to describe a particular kind of research endeavour that seeks to ask and answer questions of bioethical interest in a way that draws on the strengths of both philosophical analysis and empirical findings (Borry, Schotsmans, & Dierickx, 2005; Dunn, Sheehan, Parker, & Hope, 2012; Frith, 2010; Ives, 2014). As a result, we can view empirical ethics as an interdisciplinary approach to the resolution of practical ethical issues within the biological and life sciences, integrating social scientific empirical data with philosophical analysis. It is a discipline that seeks to achieve a balanced form of ethical deliberation that is logically rigorous and context-sensitive, thereby generating normative conclusions that are practically applicable to a problem, challenge or dilemma.

6.2.1 Why the ‘empirical turn’ in bioethics

Applied bioethics began as a dialogue between people from many different disciplines such as medicine, theology, law, social sciences, biological sciences, philosophy and humanities, about moral questions in the fields of medicine and biology. However through a process of professionalism and institutionalisation, bioethics crystallised into a discipline that became anchored in the fields of theology and philosophy (Borry, Schotsmans, & Dierickx, 2004; Salloch, Schildmann, & Vollmann, 2012). Moral philosophy, which is at the core of ethical reasoning, is often subdivided into meta-ethics, normative ethics and applied ethics. Applied ethics can further be categorised into bioethics, environmental ethics, business ethics and legal ethics for example (Jacoby & Siminoff, 2008). Normative ethics and meta-ethics primarily rely on philosophical reasoning to determine how moral agents should act and behave and to delineate moral concepts and the nature of justification in moral theory (Strong, Lipworth, & Kerridge, 2010).

In philosophy, the relevance of basic theories⁴⁴ like utilitarianism, deontology, virtue ethics or casuistry to normative analysis is assumed. In bioethics, theoretical discussions are often considered in the light of the second order principles of medical ethics (namely autonomy – respect for persons, beneficence, non-maleficence and justice) in an attempt to ground moral universalism and gain acceptability among bioethicists and medical scientists. As a result of this earlier philosophical and theological orientations, research in the field of bioethics was generally purely centred on theoretical analysis of ethical issues. This theoretical approach included the notion that philosophical reasoning and practical life experiences were assumed to be disconnected, and therefore empirical knowledge is of little or no help in deriving moral

⁴⁴ These ethical theories are discussed in chapter two, sections 4.2 and 4.3, pp. 78-88.

obligations. This notion is related to the 'is-ought' dichotomy, a belief that there is no obvious relationship between what is and what should be, or between what people approve of and what is good (Willems & Pols, 2010).

This traditional philosophical bioethics approach was criticised by social scientists who claimed that normative analysis of practical ethical issues is based on idealised, rational thought and thus is inadequate for understanding of social and cultural factors that determine what people do when they engage in their day-to-day life events (Frith, 2010; Hedgecoe, 2004; Lawrence & Curlin, 2011). This is the 'social science critique' which triggered and paved the way for a shift from pure philosophical argumentation to empirical ethics (Hoffmaster, 1994).

This critique defines bioethics as 'a highly rational, formal, largely deductive mode of argumentation which revolves around the view that moral norms are binding or prescriptive solely in virtue of their rational justification' (Hedgecoe, 2004: p124), and stresses that philosophical morality concentrates on justifying theories and pays little attention to the practical utilization of the theories. Also, this critique contests that bioethicists offer a single correct solution for each ethical dilemma which is assumed to be independent of roles of social and cultural factors, inferring an ideal of universal ethical principles (Hoffmaster & Hooker, 2009; Hedgecoe, 2004; Hoffmaster, 1992). This deficiency results in a gap which isolates bioethics from practice, undermines the validity of its claims and reduces its contributions to policy debates on ethical issues.

So, to understand groups' or individuals' choices and actions, there is need for some empirical observations that reflect how their motives, beliefs and perceptions interplay with specific ethical challenges, and how this eventually influences how they act and what they do. The dissatisfaction with normative analysis in bioethics inquiry expressed by the social science

critique calls for a whole new paradigm that grounds ethical inquiry in human experiences in the form of empirical observations to make normative conclusions relevant to practice in bioethics.

Therefore it is not surprising that the past two decades have witnessed changes in the methodology of bioethics from applied ethics, which is a predominant use of philosophical analyses based on application of rules and principles to resolve ethical issues, to a growing application of empirical methods to analysis of ethical inquiry (Hedgecoe, 2004; Hurst, 2010; Jacoby & Siminoff, 2008; Strong, Lipworth, & Kerridge, 2010; Willems & Pols, 2010). This change has been termed an 'empirical turn' or 'empirical shift' ((Barry, Schotsmans, & Dierickx, 2005; Borry et al., 2004; Willems & Pols, 2010); Hurst, 2010; Jacoby & Siminoff, 2008; Strong, Lipworth, & Kerridge, 2010; Willems & Pols, 2010). This results in empirical ethics, which is integration of empirical data and philosophical reasoning. Consequently, there has been a whole new appreciation of empirical methods in bioethics which though have their foundations in the social sciences, have become useful in bioethics not just to describe the social world as it is by focusing on a particular state of affairs that has some moral or ethical relevance, but more importantly to draw normative conclusions from empirical data (Hedgecoe, 2004; Hurst, 2010b; Willems & Pols, 2010).

In addition, this empirical turn in bioethics has been reinforced by the fact that empirical research informs ethical deliberation by describing gaps between espoused ideals and actual practices and by charting the consequences of particular ethical decisions or policies (Solomon, 2005), and also by the emergence of evidence-based medicine which emphasizes empirical research in treatment decision and the development of clinical ethics which promotes interaction between health care stakeholders with a view of identifying factors that affect ethical decision making in medical care. Summarily, the dissatisfaction with and the difficulties in applying

abstract theoretical principles to concrete healthcare dilemmas, and growing evidence that empirical research may help to generate resolutions when two or more ethical principles are in conflict, has contributed to the empirical turn (Borry et al., 2005).

This empirical trend in bioethics can be illustrated with studies which have investigated the inclusion of empirical literature in the field of bioethics. Sugarman *et al* scrutinized studies published during the 1980s for empirical input (Sugarman, Kass, & Faden, 2009). Another publication used a quantitative approach to evaluate studies published between 1990 and 2003 (Borry, Schotsmans, & Dierickx, 2006). These two attempts investigated if the number of empirical-ethical publications in the field of bioethics has been increasing and analysed the methods used in these empirical studies. The topics in bioethics that have been studied empirically and subjects of research in these empirical studies were identified and compared.

Borry and colleagues (2006) observed that only 435 of 4029 published papers in applied ethics, which represent 10.8%, used empirical design. The period between 1997 and 2003 had a higher number of empirical studies than the period 1990 to 1996. Most of the articles were published in *Nursing Ethics* (39.5%), followed by *Journal of Medical Ethics* (16.8%) and then *Journal of Clinical Ethics* (15.4%). Most of the empirical studies employed the quantitative paradigm (64.6%) while a minority used a mixed method approach (3.2%). More than half of the empirical studies that used qualitative approach were published in *Nursing Ethics* (52.9%) while most (60.5%) of those with quantitative approach were published in *Journal of Medical Ethics* and *Journal of Clinical Ethics*. Sources of data were from healthcare stakeholders – nurses, patients and physicians. The authors observed an increasing trend of ethics-related empirical studies during the period of study confirming the ‘empirical turn’. This trend was corroborated by

a study that showed a sharp increase in empirical studies in Turkish medical ethics literature during the period 1994 – 2009 (Kadioglu & Kadioglu, 2011).

As the number of ethics-related empirical research continues to increase, the contribution of empirical ethics to resolution of bioethical dilemmas becomes better appreciated. This ‘empirical turn’ needs to be properly conceptualised and integrated with ethical theory to provide a robust evidence for implementation of ethical policies. The turn in empirical research has been supported by some bioethicists but it has also been criticised by others. So, in the next section, I discuss the debate on empirical ethics.

6.3 Debating empirical ethics

6.3.1 Proponents of empirical ethics

There have been strong arguments in favour of empirical ethics, especially the relevant contribution of empirical data to the process of philosophical dialogue in bioethics (Loughlin, 2011). It is believed that the introduction of empirical evidence within the bioethical discipline has made it less theoretical and closer to reality (Pastor, 2013), by enriching normative arguments and making ethical discourse more context sensitive and comprehensive (Alvarez, 2001; Jonasson, Liss, Westerlind, & Berterö, 2011; Smajdor, Ives, Baldock, & Langlois, 2008), and making moral discourses and the formulation of policy, regulation and legislation relevant and applicable to ethical conflicts without ignoring social and cultural factors that may have contributed to such dilemmas.

Also, in support of empirical ethics is the fact that the empirical methods specifically allow the description of the attitudes, beliefs, moral opinions, reasoning patterns and decision-making of those involved in a certain practice or research endeavor. In effect, it allows the description of the experience of individuals or populations with respect to morally relevant issues

in general. For example, the information and level of comprehension required for acceptable informed consent or what is considered by participants to be acceptable risks are issues that should be addressed through empirical research because empirical methods obtain information on what people wants and what really happens. This will in turn fine-tune the best ways to achieve normative objectives, for example to discover how best to achieve the dual aims of gaining important knowledge and respecting research participants (Sieber, 2004).

The use of data in empirical ethics to describe attitudes of individuals or communities to ethical issues and to explore the likely or actual consequences of bioethical policies and decisions has been substantiated by other authors (R. de Vries & Gordijn, 2009). This can be illustrated with this example. A study that examined the public refusal to consent to DNA bio-banking among a Swedish population (Melas et al., 2010) that showed a significant mistrust of DNA biobank research related to concerns about integrity, privacy, suspiciousness and insecurity. The empirical data obtained through semi-structured interviews and structured questionnaires contributed to the ethical discussion of benefit sharing and assurance of privacy as a means for increasing personal relevance and trust among participants in genomic research.

Evidently empirical ethics aids the identification of moral issues that have escaped the attention of ethicists, but are relevant in a specific context including those that are obvious because they are embedded in practice (Davies, Ives, & Dunn, 2015; Ives & Draper, 2009). This point is further strengthened by the fact that foundations for robust social and economic development are anchored on public engagement, interdisciplinarity and innovation (Gardner & Williams, 2015). It therefore follows that an empirically derived understanding of how ethical regulations affect the stakeholders, irrespective of the various settings in which they are applied, constitutes an important component of moral research and innovation practices. The empirical

methods used in empirical ethics research provide a glimpse of peoples' experiences of illness and also enable exploration bio-socially, that is, the way in which individuals and social groups draw upon biomedical knowledge to make sense of themselves or to advance particular social and political aims. Considering the significance of empirical ethical research, it can be argued that the general need for empirical information in applied ethics is non-controversial, although the specific kind of information which is required in argumentation about certain topics is dependent on the normative-ethical background which underlies the ethical evaluation. This implies that a reflection on the ethical significance of empirical data prior to the beginning of an empirical study is desirable. Empirical ethics can thus provide the bridge between conceiving a moral vision of a better world, and actually enacting it, as empirical methodology is employed more effectively (Ebbesen & Pedersen, 2007; Solomon, 2005).

6.3.2 Opponents of empirical ethics

Empirical ethics has been criticised both in regards to its methods and purposes, and thus confronted with 'a sudden shaking at its core following a questioning of its actual identity and methodology' (Salloch et al., 2012: p. 3). From my viewpoint, the contents of criticism of empirical ethics can be categorised into two main areas: criticism of sociology by bioethicists and criticism of relevance of empirical data to moral normativity. First most bioethicists depicted sociological studies as irrelevant to their discipline because they feared being too strongly influenced by historical and sociological contextualisation, which could bog them down in cultural and ethical relativism (Mbugua, 2012; Strong et al., 2010). They believed this major concern of the possibility of obscuring normative content of research would diminish attention given to philosophical analysis while over-emphasizing empirical data. Hurst posited on this using strong terms when she stated that bioethics 'becoming an empirical discipline through a

shift to the social and neurosciences would be a turn away from normative thinking, which we would not take' (Hurst, 2010: p 439), 'we' referring to bioethicists. The bioethicists argued that while empirical ethics may map the moral domain and tell us how people behave, it cannot generate normativity or determine what is good or evil, right or wrong without the input of philosophical reasoning.

Second, bioethicists have also expressed concern about what data are and how empirical data relates to the development of moral norms (Birnbacher, 1999; Borry et al., 2004). Though this is a meta-ethical question, they believed that empirical ethics commits the naturalistic fallacy⁴⁵ and violates the fact-value distinction. Naturalistic fallacy is a concept believed to have been described by David Hume but it was named by G.E. Moore in his treatise 'Principia Ethica' in 1903. It is a concept that involves two ideas, namely: a. Appeal to nature – an idea that whatever is natural cannot be wrong; and b. Deriving 'ought' from 'is' – this is a move from a 'fact' that is a declarative or descriptive utterance, to an imperative or prescriptive utterance. In the context of my discussion, the opponents of empirical research criticised using empirical data which constitute the 'is' or 'fact' (declarative or descriptive) alone as basis for the 'ought' or 'value' (prescriptive or imperative) (Lawrence & Curlin, 2011). Empirical data is seen as 'devoid of values' and therefore cannot be interpreted in the absence of a pre-existing philosophical framework. Subsequently they pointed out that the exploratory function of empirical research in bioethics is dependent on normative-ethical presuppositions which decide if and in what sense the empirically identified issue can be seen as an ethical problem and not as a practical problem of

⁴⁵ Naturalistic fallacy often mimics good reasoning by claiming to be factually based, convincing us that everything that is 'natural' is morally acceptable, and within the context of human affairs we ought to condone it. It however does not so much recognise the interplay between fact and value (fact-value distinction) as try to reduce questions of value to mere questions of fact. For example, saying a ring is made of gold does not necessarily mean the ring is valuable unless we also know that gold is valuable.

another origin (Lawrence & Curlin, 2011). According to Diniz, empirical data may ‘give a face to abstraction’ but it fails to recognise diversities in and give reality to concepts and arguments if interpreted in isolation without ethical theoretical input (Diniz, 2015). Also the quality of empirical research conducted under the rubric of bioethics has been criticised particularly study design, method and validity (Leget, Barry, & de Vries, 2009).

From my viewpoint, most of these criticisms are not specific to bioethics but relate to research in any setting. I observed that most of these criticisms failed to appreciate the assumptions that underpin empirical ethics or misrepresent the claims that are made about its moral utility. The issues raised by the critics of empirical ethics, especially on the distinctiveness of the boundaries of sociology and bioethics disciplines, can be clarified by examining the methods used for the integration of empirical data and normative analysis.

Finding an appropriate integrative methodological approach for application of empirical evidence in ethical deliberations to arrive at normative conclusions is strategic, and the ‘navigation of these boundaries requires cooperative engagement of the descriptive and normative disciplines’ (Brown & McGee, 2014: p.325). This is more so because the enrichment that the empirical turn brings to the bioethics discipline will be transient and not fully appreciated, if not properly conceptualised and integrated with ethical theory. According to Mbugua, ‘it can easily undermine bioethics normative mandate’ (Mbugua, 2012: p 4), if not fully comprehended and developed.

6.4 Types of empirical ethics

Empirical ethics can be divided into three main types, namely; *sociology of bioethics*, *sociology for bioethics*, and *sociology in bioethics*. *Sociology of bioethics* implies a focus on bioethicists and the discipline of bioethics as objects of research. It examines the social context of

bioethical issues, for example seeking answers to sociological questions to enhance our understanding of organisations, roles, values, rituals and the place of biosciences in the society. It is an analysis of the social construction of bioethical problems and the role of social structures in shaping the way in which bioethics has developed. Here the cooperation between the bioethicist and the sociologist is traditionally based on the assumption that they are representatives of two essentially distinct scientific disciplines, with the ethicist representing the prescriptive sciences and the sociologist the descriptive sciences. The latter collect and present data, then the former discuss the value issues, the associated moral principles and the possible moral consequences of these facts. This is an important type of empirical ethics as it encourages bioethicists to reflect on their place in the world. Sociology of ethics can be viewed as a free agent operating from the outside of the bioethics circle, one whose questions and research are guided by a desire to understand the social forces that shape the way a society organizes moral advice-giving. This helps bioethicists to reflect on the meaning and value of their work.

Sociology for bioethics denotes a type of empirical ethics that produces data for bioethics, and these data can range from descriptions of historical origins or current ethical debates to information about how people in different cultures and at different social levels actually behave in ethically problematic situations. So social scientists provide bioethics with data which are used as factual component of ethical arguments, based on the premise that ‘good ethics depend upon good facts’(Raymond De Vries, 2004). For example, Doukas *et al* investigated the key values and beliefs about genetic testing for prostate cancer risk in anticipation of its future availability using a series of focus groups. They concluded that ‘identifying these men’s values will help health professionals anticipate the informational and ethical needs of patients in the informed consent process. Men will need to understand how such testing may affect their planning regarding future

prostate health, and how medical information is used outside of the physician-patient relationship (Doukas, Fetters, Coyne, & McCullough, 2000). In practice, the qualitative data obtained from this study provided the empirical evidence which guided the ethical process of obtaining consent from men who were genetically tested for prostate cancer risk.

This type of empirical ethics can also be used to identify moral issues that need to be investigated. This can be illustrated with a study that showed that doctors rarely choose between prolonging life and euthanasia. Often the primary decision is whether or not to do everything to prolong life rather than whether euthanasia is acceptable in this circumstance (Musschenga, 2005). The findings of this study pointed out the ethical challenges in the end-of-life care that require further investigation. Furthermore, sociology for bioethics can be used to assess the possible consequences of actions or particular policies by providing data on them, making it relevant to utilitarianism. Blendon *et al* investigated how the public feels about efforts to restrain healthcare costs by limiting the use of high-cost prescription drugs and medical/surgical treatments. The study revealed support for decisions that limit the use of high-cost prescription drugs or treatments when some other drug or treatment is available that works equally well but costs less, but little support for decisions in which prescription drugs or treatments are denied simply because of cost. So the authors concluded, based on this empirical evidence, that the public could distinguish in practice between the concepts of comparative effectiveness and cost-effectiveness analysis (Blendon, Benson, Botta, Zeldow, & Kim, 2012). The empirical data from this survey shows the consequence of implementing an unpopular healthcare policy.

Sociology in bioethics breaks the boundary between empirical evidence and ethical theory as empirical and ethical analyses occur in an iterative manner (Frith, 2008). This is the type of EE that employs methodologies which integrate theoretical reasoning and empirical data. Facts

produced by empirical science are not value neutral, as values play a role in how these data are constituted. Furthermore, the theories are assumed to be fact laden. Therefore, ethical theories are based on ‘background empirical assumption’. This type of empirical ethics offers the best chance, at least in theory, of genuinely assessing the strengths of both empirical and the philosophical contributions and has received the most methodological attention.

For my study, I employ the sociology in bioethics type of empirical ethics. My thesis makes use of a method that integrates empirical evidence and ethical principles. This aids ethical analysis as attempts are made to express how certain principles may be formulated and used in practice as guidelines and thus show how empirical data could initiate or change our understanding of ethical principle and theory within the context of informed consent process and dynamics of community engagement in genomic research. In the next section, I discuss the models of methods employ in sociology in bioethics. These models aim at the integration of empirical and normative analysis in bioethics.

6.5 Integrating empirical and normative analysis in bioethics: the methodological models

What connection or integration there is between ethics and empirical research, and what it means in practice has been queried. This is a fundamental issue as it underpins the utility of empirical evidence in ethical deliberations. There are assumptions made when conducting empirical research in bioethics (Borry et al., 2004). It is often assumed that ethically meaningful information can be gained from the study of people’s expressed attitudes, moral beliefs and intuitions, reasoning and behaviour. This is particularly relevant in empirical studies that employ qualitative methods such as interviews and ethnographic observations (either participatory or non-participatory). In interviews, the expressed views or beliefs of the individuals constitute the data for analysis. If the information obtained from the interview process is not meaningful then

the data are unusable. It is also assumed that the primary outcome of empirical data is not the generation of moral truths or norms, but engagement with an ethical issue in a practical and direct way. This is fundamental to the relevance of empirical ethics discipline to practice, as well as contributory to the construction of normative conclusions which are morally justifiable and context-relevant. It is therefore essential to plan an empirical study in bioethics on a sound epistemological foundation and use an appropriate methodological framework.

Three important questions should be considered when planning empirical ethics study. These are: a) how a normative conclusion can be justified; b) the analytic process through which that conclusion can be reached; and c) the kind of conclusion that is sought. This is important because these questions aid in selection of empirical-normative methods for generating normative assertions (Davies et al., 2015). The answers to these questions prior to commencement of an empirical study in bioethics will commit the researcher to a specific empirical ethics methodology which will in turn demonstrate alignment with a particular epistemology about how a claim to moral knowledge can be justified.

In addition to employing empirical knowledge and theoretical reasoning to construct normative statements, the application of empirical bioethics to my research aimed at achieving two goals. First, I use empirical data and ethical theories in a mutually beneficial and iterative manner to arrive at conclusions which not only answer my research questions but also make my subsequent ethical recommendations serve as potential ethical solutions to dilemmas encountered in genomic research. In other words, the qualitative data from interviewing my study participants and the focus groups provide the framework for the integration of ethical theories. Second, these empirical observations serve as a source of critique of application of ethical theories to the conflicts encountered within the context of genomic research. This allow for scrutiny of the

existing ethical principles and determine their appropriate application to the context-specific scenarios encountered in genomic research.

6.5.1 Types of methods

Four types of methods have been proposed for integrating empirical research and normative ethics, with some prioritizing moral theory and others empirical data (Molewijk, Stiggelbout, Otten, Dupuis, & Kievit, 2004). This typology distinguishes methods based on locus of moral authority, using this premise to clarify how best to arrive at a normative conclusion. The four types described are: (A) Giving complete authority to moral theory, and only use empirical data to provide evidence for premises or support factual claims (which conforms with sociology for bioethics); (B) Giving precedence to moral theory but accommodate a one-way relationship between theory and data such that empirical research can be used to refine theory; (C) Giving equal authority to both theory and data, with that both theory and interpretation of data can be adjusted in light of the other, or (D) Removing theory altogether from ethical analysis and focus only on the particulars, which are identified through empirical research (Molewijk et al., 2004).

From my viewpoint, this typology appears to be a continuum with full weight given to moral authority at one end of the spectrum and full weight to empirical analysis at the other end. The lack of normative analysis in empirical research ethics result in purely descriptive studies which are characterised by a missing link between the empirical research and the ethical debate. The ‘middle of the spectrum’ type C appears to be more acceptable as it allows for equal weight to both data and theory. The type A downplays the significance of empirical observations while type D lacks normative analysis altogether. The type B is not likely to allow for robust interaction between theory and data as the one-way approach may neither explain the empirical observations

nor validate an existing ethical theory. If this is assumed, then the normative assertions are likely to be flawed.

6.5.2 Methodological frameworks

Explicit connection between empirical data and normative reflection is a criterion for good quality empirical ethics research (Salloch et al., 2012). So, to integrate empirical findings with normative analysis, I discuss three conceptual methodological models or frameworks which are appropriate for empirical-normative integration. These models not only propose a balance between empirical and ethical analysis and emphasise normative conclusions but acknowledge that ethical conflicts can be resolved, and social practice adjudicated by both the gathering of empirical data and normative ethical analysis, thereby conceptualising the interaction between both elements in a plausible and systematic way. The first two models: pragmatic hermeneutics and reflective equilibrium; achieve moral justification either through consensus or coherence. There has been a call for combining these two methodologies for simultaneous use in empirical ethics (Davies et al., 2015; Ives & Draper, 2009). The third model, symbiotic empirical ethics, is based on a naturalistic conception of ethical theory that sees practice as informing theory just as theory informs practice. This model is distinctive, non-restrictive and balanced.

6.5.2.1 Pragmatic hermeneutics

This method is a form of interactive dialogue since it relies on attention to communication and theory of meaning that derives from the practical consequences of its usage and concepts. This method is essentially based on consensus. A method that appeals to consensus to justify a normative conclusion finds moral authority in agreement of some kind. Consensus (which often is dialogical in approach) relies on accepting the view that a process of dialogue can lead to people understanding the world in the same way which leads to agreement on the solution. The

normative conclusion generated through that dialogical process becomes the findings of the study. The contents of dialogue are subject to personal or group interpretation rather than objective truth. This makes normative orientation of day-to-day activities explicit (Frith, 2012). The researcher can then produce ethical arguments which the data provides the evidence to evaluate.

This approach allows theories to be directly related to the practices under consideration, so they are locally based and embedded in the specific practice under study. Alternatively, a modified approach seeks a different kind of consensus: one based on a philosophical claim about democratic authority rather than a meta-ethical claim about shared interpretation and moral knowledge. For this approach, agreement is not the basis but the legitimacy of the democratic process which is invoked to draw normative conclusions (this is deliberative democracy). The major drawback of pragmatic hermeneutics is that it gives lesser normative role to ethical theory thereby leaving future readers of any conclusion made from the study uncertain if the study findings have normative authority (van der Scheer & Widdershoven, 2004; Widdershoven, Abma, & Molewijk, 2009)..

6.5.2.2 Reflective equilibrium

This is a methodological approach that integrates theory and practice, based on Rawlsian reflective equilibrium which was employed to provide justification for moral theories and principles (Rawls, 1979). It involves balancing, that is an attempt to match, prune, and adjust empirical evidence (considered judgements) in order to render coherent with the premises of ethical theories (general moral commitments). In empirical ethics research, it is employed by first mapping the study participants' views and beliefs (people's considered judgements) and then formulating 'a well-considered judgement' consistent with their responses on other issues using

reflective equilibrium for determining whether a set of principles that forms the core of an ethical theory is in alignment with the well-considered judgements of the participants. It is essentially a coherent moral view that criticizes the foundationalist conception of ethical theories by constructing theory in the light of experience (Cooper, Bissell, & Wingfield, 2007; Frith, 2012). Though it integrates empirical data and ethical theories and is applicable to solving ethical problems in concrete situations, the normative conclusion is based on moral justification grounded in rationality of human experience.

Coherence finds moral authority in rationality and consistency. This has to do with coherence with a moral theory that is logically relevant to a particular theoretical viewpoint. This could be achieved through either traditional philosophical (analytic) approach where coherence is found between data and theory, or reflective equilibrium where coherence is sought by conducting analysis and generating normative conclusions through a consultative approach. The researchers consider if they will prioritise the thinker, theory or the stakeholder when planning their methods of analysis. Reliance will be placed on a single central person if prioritising the thinker, often the researcher or research team takes the analytic burden. This is usually consultative. To prioritise the theory, a person is required to conduct analysis but the focus is on logical, consistent development and application of theory such that theory dominates the normative analysis. This kind of method generates conclusions that will be binding on all rational agents (at least all rational agents who subscribe to that theory thus expressed), once the theory is agreed upon. This is an attempt to use data to help refine theory, and then apply the more contextualised theory to the problem in hand, rather than deciding on the theory in advance of the research process.

The prioritisation of stakeholders connotes that the analysis is the product of a group process that connects a broad range of voices to link relevant practical experiences to ethical considerations in a range of differently structured facilitative processes like focus groups discussion or interviews. The role of the researcher is less central, and becomes more one of facilitation than substantive analytic contribution, such as in the dialogical approach. The researcher does not generate or own the normative conclusions but rather discovers and communicates the conclusions reached through the research process (Davies et al., 2015; Mertz et al., 2014).

Unfortunately, reflective equilibrium is limited by a) lack of sufficient latitude since it may be inapplicable to general exploratory research that considers people's account of what they do and how they conceptualize their practice, b) idealization of human rationality, c) vagueness of concept of coherence, and d) the tendency to fit people's views into predetermined theoretical categories which might not reflect their thinking.

6.5.2.3 Symbiotic empirical ethics

This is an integrative model proposed by Frith (2012). It is a naturalistic account of ethical theory which allows for the recognition of particular circumstances in which the ethical decision takes place while not separating the empirical contingencies from the ethical enterprise. This model emphasises the relationship between practice and theory in ethical discourse as 'practice informs theory just as theory informs practice', they exist in a symbiotic relationship (Frith, 2012: p 198). It advocates five elements which can be used for integration of empirical data and ethical theory to draw normative conclusions. These elements include: setting out the circumstances, specifying theories and principles, using ethical theory as a tool of analysis, theory building, and making normative judgements.

The first element of ‘setting out the circumstances’ emphasizes a ‘take-off point’ similar to Aristotle’s *endoxa*, the phenomenon. The phenomenon implies the views, opinions and aspects on the ethical issues under deliberation, and the fact that the circumstances in which these issues are located should be considered first. This allows for a thorough description of the issues under enquiry. In the setting of a genomic research, for example, asking questions that seek to define the goals of the research while defining the views, beliefs and opinions of research participants on how their biological samples are handled permits a socially construed setting of the ethical dilemmas under investigation. This is the starting point. This helps to ‘set out the circumstances’ of the empirical study.

With respect to the second element, ethical principles have to be specified in a particular context. This diminishes the abstractness of these principles while they become ‘practical guides for action’, that is become relevant in practice. This can be illustrated using the ethical principle of individual autonomy in the research setting. Contextualizing the concept of individual autonomy in the setting of communitarian ethos aids in circumventing friction between ‘individual consent’ and ‘community agreement’ or ‘group consent’. So specifying the principle within the Aristotelian tenet that, as stated by Frith, ‘*it is the particular situation that is the measure of an ethical principle and the principle needs to be adapted to both fit the situation and to be made meaningful*’ (Frith, 2012: p 202), makes collective communal input to individual autonomous choices better understood. It is not mistaken for violation of principle of respect for persons.

The ethical theories that applied to real life circumstance, like in ethical dilemmas encountered in research or health care settings, can be used as tools for analysis in the sense that they can be applied during empirical analysis ‘*to discern areas of disagreement, clarify terms and*

reveal ambiguities' (Frith, 2012). This allows for robust evaluation of interaction between empirical data and ethical principles towards making normative conclusions. It is important to note that ethical theories are not pre-determined static entities but are developed by the interaction of reason and experience so making them empirically oriented. The element of theory building is consequent on the use of ethical theories as analytical tools. As existing ethical theories are applied during analysis it becomes a refining process to evaluate the theories in the context of empirical data making it possible to either formulate new theories or modify existing theories. So, in effect theory can be used to approach data and can also arise from the data. Finally, the making of normative judgments is what makes bioethics discipline relevant to practice. Having applied ethical theories to data and data to ethical inquiries, as stated earlier, judgements can be made about ethical issues. Normative conclusions reached after this process are thus defensible, consistent with what bioethics seeks to achieve in the first place, being able to give reasons for our actions.

Comparing and contrasting these three empirical-normative methodological analytic models, it is obvious that the symbiotic empirical ethics (SEE) model addressed the drawbacks or limitations of the first two, pragmatic hermeneutics and reflective equilibrium. The SEE model appears 'across-the-board', thus providing a framework for comprehensive integration of empirical data and ethical theory. For example, the leaning of pragmatic hermeneutics approach towards generation of normative conclusions on the basis of consensus, anchoring moral authority on agreement of empirical evidence weakens the significance and contribution of ethical theory to normative conclusions. This limitation is taken care of by the SEE model as theory is employed as an analytical tool thereby ascertaining its influence on moral justification and normative assertions. Similarly, the SEE model addresses the limitations of reflective

equilibrium by seeking to achieve theory building beyond the scope of ‘well-considered judgements’ of research participants to allow for application and generalisation of normative deductions to similar ethical scenarios and dilemmas.

6.5.3 Situating my research within these models

Adopting an appropriate methodological model for my research required careful consideration of my goals, the definition and description of my research problems, the kind of normative conclusion I sought for and how I proposed to justify this conclusion. Though most of these methodological frameworks could have been entrenched at varying levels of my research I adopted the SEE model, employing its five elements.

As regards my thesis, the exploration of the views, perspectives and beliefs of potential research participants and biomedical researchers of genomic research enterprise offered a good and detail description of the ethical issues for subsequent analysis and reflection. The existing ethical theories and principles which were applicable to the situation under investigation, that is the genomic research setting, were specified and applied to determine their suitability and meaningfulness. These theories in effect were used as a tool of analysis by seeking for areas of conflict and consensus between the ethical theories and the empirical observations.

Empirical data derived from the qualitative methods, for example, was used to describe the attitude of research participants to informed consent process in genomic research, explore their beliefs and perception of ethical issues like storage and export of human biological specimens, and identify how the communal value system influenced engagement in genomic research. The responses of the participants served as a reflection of likely consequences of ethical policies that evolved from the research conclusions and recommendations, and thus gave better

understanding of the relationship that existed between their values as participants and our practice as scientists (the ‘is’) on one hand and ethical expectations (the ‘ought’) on the other hand⁴⁶.

Consequently, the responses from these stakeholders served as a template for theory building after theories and principles were iteratively applied to the data, in such a way as to fit the empirical and theoretical analyses to the ethical issues of informed consent and community engagement in genomic research. Eventually normative judgements were made based on the conclusions. In conclusion, the adoption of the SEE model with the application of its five elements allow me a more comprehensive socio-empirical analysis with intuitive ethical deliberation and eventual acceptable normative conclusions that could be relevant to practice.

6.6 Conclusion

This chapter defines and elaborates on empirical bioethics and justifies why I chose the empirical approach for my thesis, where my thesis is situated within the existing methodological models and how I apply the symbiotic empirical ethics model for my theoretical integration to draw normative conclusions. Empirical turn in bioethics research has gained significant momentum with more qualitative researchers employing empirical methods as reflected in increasing numbers of publications. Application of empirical approach to ethical inquiry has improved the robustness and meaningfulness of outcome of bioethics research allowing for better understanding of life experiences to answer research questions, and also for integration of qualitative data and philosophical theories to reach normative conclusions. In the next chapter, I discuss the methods I employed for conducting my study.

⁴⁶ I discussed the ‘is-ought’ debate/dichotomy under section 6.3.2 on p. 116

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PART TWO

INTRODUCTION TO THE STUDY

CHAPTER 7

METHODOLOGY

7.1 Introduction

In this chapter, I discuss the research methods used for conducting the interviews and focus group discussions, and for analyzing the data obtained from the potential research participants and biomedical researchers in my thesis. In addition, I justify my decision to use qualitative inquiry and methods to answer my research questions. Thereafter, I define qualitative research, its application to research in bioethics, and discuss the relevance and details of the methods I used. Also, in this chapter, I discuss the step-by-step implementation of my project including the intricacies of the methodologic approach and data collection. Finally, I deliberate on the analytical method I use to draw conclusions from my data.

7.2 Qualitative research

7.2.1 Definition of qualitative research

Qualitative research is diverse because of its relevance to different disciplines and professions. This makes it difficult to have a succinct definition. According to Robert Kin, ‘too brief a definition will seem to exclude one discipline or another, and too broad a definition will seem uselessly global’ (Kin, 2011: p7). So, there is no globally acceptable definition. However, qualitative research is considered a type of scientific research that seeks to understand a given research problem or topic from the perspectives of the local population it involves (Finlay & Ballinger, 2006; E. Murphy, Dingwall, Greatbatch, Parker, & Watson, 1998). The word ‘qualitative’ implies an emphasis on the quality of entities and on processes and meanings that are not experimentally examined or measured in terms of quantity, amount, intensity, or frequency (Denzin & Lincoln, 2000). Instead of seeking a universally acceptable definition, qualitative research is defined in terms of its unique features or characteristics.

Qualitative research is valuable for studying meaning, that is, what is important to people based on their knowledge and experience and seeks answers to questions that stress how social experience is created and given meaning (Chandler, Reynolds, Palmer, & Hutchinson, 2013). Qualitative research methodologists identified key elements that define qualitative research and how these elements are applicable to investigation of a research problem (Merriam, 2009). According to Lawrence Berg (2012), the qualitative research design is *naturalistic* because it ‘refers to studying real-world situations as they unfold naturally’, implying that it is not manipulative. Therefore, the researcher is open to whatever emerges as there is no predetermined constraints on findings. The design is also different from quantitative research because it is *emergent*, that is it accepts adaptation as understanding deepens and situations change during the inquiry process. This allows the researcher responds to opportunities to pursue new paths of discovery as they emerge (Berg, 2012; Kin, 2011).

Data collection in qualitative research often yields detailed ‘thick description’ observations, for example qualitative methods like interviews capture direct quotations about people’s personal perspectives and lived experiences. The collection process also demonstrates *empathic neutrality* by showing openness, sensitivity, respect, awareness and responsiveness in working with study respondents. Attention is given to process, assuming change is ongoing during the data collection (Denzin & Lincoln, 2000; C. Marshall & Rossman, 1995; Merriam, 2009). Indeed, the great contribution of qualitative research lies in being culturally specific and the contextually rich data it produces. Finally, the analysis in qualitative research is *inductive*, has a *unique case orientation* and is *context sensitive*. It is research that places findings in a social, historical and temporal context by carefully considering the meaningfulness of generalization across time and space. This is accomplished by immersion in details and specifics of the data to

discover important patterns, themes and inter-relationships (Curry, Nembhard, & Bradley, 2009; Hudon et al., 2014; Mack, Woodsong, McQueen, Guest, & Namey, 2011).

Before I discuss the rationale for choosing a qualitative approach for my thesis, I first discuss the relationship between qualitative and quantitative research, the relevance of qualitative research in bioethics, and the theoretical framework for my thesis.

7.2.2 Relationship between qualitative and quantitative research

The relationship between qualitative and quantitative research can be viewed from two angles, first as being epistemologically different, and second as being complementary in which case both can be used together either concurrently or sequentially, as in mixed-method approach. The first approach distinguishes the two based on philosophical beliefs, that is, qualitative research uses a naturalistic approach that seeks to understand phenomena in context-specific settings whereas quantitative research is based on logical positivism and uses experimental methods and quantitative measures to test hypothetical generalisations (Curry, Nembhard, & Bradley, 2009; Hudon et al., 2014; Natasha Mack et al., 2011). Each represents a different inquiry paradigm, and researcher actions are based on the underlying assumptions of each paradigm. The second approach sees them as complementary, meaning that qualitative research is used to gain understanding of underlying reasons, opinions, and motivations and thus provides insight into the problem or helps to develop ideas or hypotheses for potential quantitative research, using typically a small sample size and respondents selected to fulfil a specific sample criterion. Concurrently or sequentially, quantitative research is used to quantify the problem under investigation by way of generating numerical data or data that can be transformed into useable statistics, and emphasize the measure and analyses of causal relationships between

variables not processes. Quantitative research uses measurable data to formulate facts and uncover patterns in research. These attributes distinguish qualitative from quantitative research.

Though quantitative methods have been used to examine outcomes of medical care interventions and policies on health issues including ethics, it has become more apparent that 'quantitative methods are not as well suited to examine the complex aspects of the healthcare delivery system such as patient perception of quality of care, clinical leadership in implementing evidence-based guidelines, and organisational change which are critical issues' (Curry, Nembhard, & Bradley, 2009; p. 1442), when compared with qualitative approach in health services research. To support this assertion, Cronbach states that 'the time has come to exorcise the null hypothesis' (referring to quantitative research) because it ignores effects that may be important and does not take into full account the many interaction effects that take place in social settings (Cronbach, 1975, p.124).

The major differences between the two research approaches have been summarized as conceptual and methodological (Creswell, 2009). Conceptually, qualitative research is concerned with understanding human behaviour from the informant's perspective while quantitative research is concerned with discovering facts about social phenomena. Methodologically, qualitative data are collected through participant observation and interviews, analysed by themes from description by and in the language of the informants whereas quantitative data are collected through measuring things, analysed through numerical comparisons and reported using statistical analysis (Creswell, 2009). However, the choice of which type of research to use should be driven by the research questions that need to be answered, the appropriateness of the methods to be used, and the type of data that the researcher seeks.

7.2.3 Qualitative research in bioethics

In depth exploration of how people think, make decisions, communicate and behave are closely linked to the ethical challenges or dilemmas that arise in research settings. This calls for an approach that examines a research problem from several different points of view (Miller, 2013), that generates detailed data which leave participants' perspectives intact, and provide multiple contexts for understanding the phenomenon under study. Over the years, qualitative methods have become increasingly popular in investigating bioethical inquiries. Similarly the analytical element of qualitative research is frequently used and becoming more prominent in bioethics literature (Jacoby & Siminoff, 2008; Pearlman et al., 1993).

Ethnography, a qualitative method of inquiry, was in fact one of the first methods used to conduct research on bioethical issues. According to Gordon and Levin⁴⁷, 'bioethical issues and dilemmas are morally charged, laden with meaning, and unfold through social interaction, therefore ethnographic research is ideal for opening the door to the world of meanings attributed to health-related events and moral decisions, and for understanding the broader socioeconomic and political factors shaping our cultures and cultural members frame, interpret, and respond to such phenomena' (Gordon & Levin, 2008: p.84 in Jacoby & Siminoff, 2008). It is a method that aims to understand the meanings that individuals attach to situations or events under study, as a result it is well suited to the study of bioethics (Jacoby & Siminoff, 2008).

⁴⁷ Gordon and Levin in their chapter 'Contextualizing Ethical Dilemmas: Ethnography for Bioethics' in *Empirical Methods for Bioethics: A primer* (eds. Jacoby & Siminoff) presented the contributions of ethnography to bioethical research, and pointed out its strengths and weaknesses. They stressed that 'its strength lies in being appropriate for contextualizing bioethical issues in their broader social, historic, economic, political, ideological, and cultural contexts' (p.110) but it is flawed by being 'time-consuming, expensive, and resource intensive, and that personal biases may be introduced into data collection and analysis processes' (p.111).

Similarly, other qualitative methods⁴⁸ like interviews and focus group discussions have also been employed in bioethics. Interviews provide an adaptable means of gathering data needed to conduct bioethics research. Semi-structured interviews especially have been used effectively to examine several topics, including genetic testing (Marshall et al., 2014), end of life care (Martin, Lavery, & Singer, 1999), and informed consent (Marshall et al., 2014; Vallely et al., 2010).

For example, Killawi et al (2014) used field observations and interviews to understand the procedures of recruiting, obtaining informed consent, and compensating research participants in health research in an extremely high-density multicultural setting of Qatar. They identified how potential research participants perceive research participation and how applicable ethical principles to their participation required flexibility and culturally informed adaptations (Killawi et al., 2014). In another study that illustrates the use of interviews in bioethics research, Ssali, Poland and Seeley (2015) explored the experiences and perceptions of informed consent process among volunteers taking part in two HIV clinical trials (Ssali et al., 2015). These methods provided the researchers with the perspective of the participants thus allowing a more in-depth view of the lived world that cannot be experienced in numerical data and statistical analysis.

Qualitative researchers posit that focus groups are a data collection method effective in learning the social norms of people, illuminate their opinion, and well suited for socio-behavioural research, including bioethical inquiry, that will be used to develop policies that meet the needs of a given population (Mack et al., 2011). This assertion was corroborated by Simon and Mosavel⁴⁹ (2008: p.63) when they stated that ‘focus groups are a versatile and useful tool for

⁴⁸ Details of my data collection methods and how they relate to grounded theory are discussed below

⁴⁹ This paper on ‘Ethical design and conduct of focus groups in bioethics research’ is one of the contributions in *Empirical Methods for Bioethics: A primer* edited by Jacoby and Siminoff.

bioethical inquiry, as successful focus groups shed light on the diversity of views, opinions, and experiences of individuals and groups' (Jacoby & Siminoff, 2008). A good illustration is the study on 'Talking about human genetics within religious frameworks' by Harris et al (2004) that examined lay public's construction of meaning associated with religious faith and human genome project, and its significance to health and diseases using results of 17 focus groups. The results of this study shed light on the diversity of opinions of the African Americans when compared to European Americans, revealing a range of lay epistemologies that suggest how religious faith may impact individual perceptions with some consistent differences in discourse between the two groups (Harris, Parrott, & Dorgan, 2004), a finding that has ethical and practical implications for health promotion, care and counselling especially as regards genomic medicine.

Qualitative research may also use multiple methods simultaneously, including in-depth interviews, focus group discussions and observations, to investigate phenomena of interest. For example, Tindana et al (2012) employed these three methods to evaluate consenting process to genetic and genomic research in a rural setting in Ghana, with emphasis on the MalariaGEN project⁵⁰, and this facilitated a robust understanding of the views of the study participants and how their expectations of the benefits of genomic and genetic research contribute to their decision making (Tindana et al., 2012).

7.3 Theoretical framework

The methodological design of my study, and theoretical framework for data collection and analysis, are underpinned by a form of Grounded Theory (GT). GT is a research approach,

⁵⁰ The MalariaGEN project is a large-scale network of genome-wide association (GWA) studies to identify genetic variants that are associated with resistance or susceptibility to severe malaria. It compares genetic markers throughout the genomes of patients with malaria and of healthy individuals from the same populations searching for differences between these two groups that correlate with resistance to disease. The project recruited mothers and affected children (with severe malaria who are on therapy) and required collection of blood samples.

developed by two American sociologists Barney Glaser and Anselm Strauss in the 1960s (Glaser & Strauss, 1967), in which data collection and analysis take place simultaneously. Each part informs the other, to construct theories of the phenomenon under study. It openly explores and analyses inductive data and subsequently develops a theory grounded in data. It is the systematic generation of theory from systematic research.

Historically, the epistemological root of Grounded Theory was mixed in positivism, pragmatism and symbolic interactionism (Glaser, 1998; Thornberg, 2012; Thornberg & Charmaz, 2014). The Glaserian and Straussian versions⁵¹ of Grounded Theory, which typify classical grounded theory, has been criticized for its naïve realist view of data (that is, implying that data could speak for itself) and the possibility of obtaining objective data by looking at many cases on the same phenomenon, when jointly collecting and coding data, to correct for bias and make the data objective (Corbin & Strauss, 2008). Hence, Charmaz (2009) developed a constructivist version of Grounded Theory, rooted in pragmatism and relativist epistemology, which assumes that neither data nor theories are discovered but researchers construct them as a result of their interactions with their participants and emerging analyses (Charmaz, 2009). The central tenet of constructivist grounded theory is to give voice to participants as it incorporates the multiple voices, views and visions of research participants in rendering their lived experiences (Charmaz, 2008). This results in a more diffuse theoretical product which does not center upon a core

⁵¹ Glaser and Strauss parted ways because of methodological disagreements and this resulted in the two versions; while Strauss allows a more flexible approach allowing the researcher to bring research questions and evidence from the literature to the field (Straussian GT), Glaser rejected starting the research process with a research problem followed by research questions rather the interest of the researcher should be to answer the questions of 'what is the participants' main concern, and how is this continually processed or resolved in the research setting?' (Glaserian or Classical GT). (Breckenridge, 2015, p.3)

category unlike classical grounded theory that aims for a core category (Appleton & King, 2002).

Grounded theorizing represents a particular version of the link between data and theory statements, emphasizing their interdependence and proposing that theory can in fact be generated from close examination of data (Seale, 1999). This inductive method, though proposes a particular way of linking theory to data, cannot work if statements made in the theoretical realm do not have clear and well-understood linkages with researchers' observations. So, it stresses the continual cycling back and forth between theory construction and examination of data. Gathering and analyzing of data are done in parallel throughout the entire project in such a way that open exploration of data and inductive analysis result in a theory grounded in the data (Thornberg & Charmaz, 2014).

Furthermore, grounded theory emphasizes the experiences of participants, the meaning of these experiences to participants and their understanding of events, as opposed to seeking confirmation of the researcher's hypotheses. It also aims to generate a theory of the phenomenon in question, such that an explanatory account that combines the rich description of processes with how various actions and structures lead to specific outcomes of interest is produced, thus making grounded theory applicable to the goal of my study. Summarily, the practical steps of Grounded Theory⁵² are as follows: a) conducting of data collection and analysis simultaneously in an iterative process, b) analyzing actions and processes rather than themes and structure, c) using comparative methods, d) drawing on data in service of developing new conceptual categories, e) developing inductive categories through systematic data analysis, f) emphasizing theory

⁵² Breckenridge (2015) and Hoffman-Miller (2016) discussed the practical steps of Grounded theory in their respective treatises 'Doing Classic Grounded Theory: The Data Analysis Process' and 'Guiding the Development of a Dissertation Research Design Using Grounded Theory'.

construction rather than description or application of current theories, g) engaging in theoretical sampling, h) searching for variation in the studied categories or process, and i) developing a category rather than covering a specific empirical topic (Breckenridge, 2015; Hoffman-miller, 2016).

To develop a theory from my data, I used the constant comparative method for analysis. The constant comparative method is a data-analytic process whereby each interpretation and finding are compared with existing findings as it emerges from the data analysis (Boeije, 2002; Kolb, 2012). I employed data collection methods⁵³ that fitted my research questions and ongoing data analysis. Hence, I developed concepts from my data by coding and analyzing at the same time, thus combining systematic data collection, coding and analysis with theoretical sampling in order to generate theory. In constant comparative analysis, coding begins directly as researchers first gather data, and they engage in this interplay between data collection and coding throughout the research project. Codes are created by defining what the data are about. Coding consists of at least two phases, the initial and focused coding (Kolb, 2012). The initial or open coding involves comparing data with data, exploring interpretation of data in a flexible manner, constructing short, precise and simple codes, and moving quickly and carefully through the data. Every code generated must fit the data rather than forcing the data to fit the code. Coding aids in seeing the familiarity between data, gaining distance from researcher's as well as study participants' assumptions, avoiding forcing data into preconceptions, and focusing further data collection. This eventually helps to confirm and saturate emerged codes and minimize missing important codes or significant details in data (Glaser, 1998).

⁵³ Data collection methods is discussed in section 7.4, p. 151

Following this initial coding, the researcher discovers the most significant or frequent codes that make the most analytical sense, so in focused or selective coding these codes, now focused codes, are used to sift through large amounts of data. During selective coding, the researcher explores and decides which codes best capture what is seen happening in the data, and these codes are raised as tentative conceptual categories. This process gives these categories conceptual definitions, and thus assessing relationships between them becomes practicable. The generation and refining of categories entails constant comparing and grouping codes, comparing different incidents, comparing data from the same or similar phenomenon, action, process in different situations and contexts, comparing different people i.e. their beliefs, situations, actions, accounts or experiences, comparing data from the same individuals at different points in time, comparing specific data with the criteria for the category, and comparing categories in the analysis with other categories (Charmaz, 2009).

The core category does not necessarily explain all the patterns of behaviour under investigation, but rather accounts for one particular behaviour that is highly relevant for participants within an area of ethical concern (Breckenridge, Jones, Elliot, & Nicol, 2012). Summarily, constant comparison method entails: a) comparing incidents applicable to each category; b) integrating categories and their properties; c) delimiting the theory; and d) writing the theory.

Further, analysis using the symbiotic empirical ethics approach⁵⁴ enables an integrated theoretical product which forms the basis for normative conclusions presented as ethical guidelines for practice. Hence, in my study, I sought to understand how and why my study

⁵⁴ Details of how symbiotic empirical ethics approach is used to arrive at normative conclusions has been discussed in chapter six, section 6.5.2.3, p. 127.

participants make decisions to participate, and what their expectations were about how researchers could engage communities, in genomic research; constant comparative method thus allowed for thematic coding of their views and opinions thereby gaining contextual understanding of the phenomena of interest without undermining their perspectives. The conceptual understanding of the factors that predicted their behaviour and practices was useful in inductively identifying and generating theories on how social variables like gender, religion, cultural beliefs, customs and life experiences affected their choices. This gave me insights into participants' behaviour, that could be used for the formulation of ethical guidelines that would aid successful implementation of genomic research.

So, the focus of my analysis was not to tell participants' stories, as in constructivism, but to identify and explain conceptually ongoing behaviour which sought to resolve important ethical concerns. This did not mean that I discarded the participants' perspectives but their perspectives, which influenced their behaviours, were explored at a conceptual level. It is this conceptual level that enables the grounded theory categories to transfer to different situations, not on account of transferring descriptions from one unit to another but in the modifiability of concepts within different settings (Breckenridge et al., 2012). In the next section I discuss my data collection methods and relate them to the epistemological foundation of my theoretical framework.

7.4 Data collection methods

I obtained data by interviewing and conducting focus group discussions on key players within the 'sphere of phenomenon of interest'. In this section, I discuss interviews and focus group discussions.

7.4.1 Interviews

Interviews serve as a means of data collection that partly reflects the recognition that people do not merely respond to stimuli but act on the basis of their interpretations of the world around them and their experiences within it (Roulston, 2014). So, such interpretations are accessed through interviews to discover what people think about the world they live in, how they evaluate their experiences within it and why they behave as they do. Therefore, for me to understand what my research participants think, believe and how they construct meaning, I need to ask them.

There are three types of interview, namely; a) *the standard schedule interview (also known as structured)* – in which the wording and order of all questions is exactly the same for every respondent and the instrument (interview guide) is administered in the same way to all respondents; b) *the non-schedule standardized interview (referred to as semi-structured)* – in which the interviewer works with a list of the information required from each respondent but the particular phrasing and ordering of questions is adapted to suit individual respondents; and c) *the non-standardized interview (also known as unstructured)* - in which no specific set of questions is employed and questions are not asked in any particular order (conversational).

A preoccupation with the standardization of the interview process has been criticized for its leaning towards positivism, in that it is too concerned with eliciting facts which exist ‘out there in the world’ from respondents. Other critics have pointed out the dilemma encountered when the interviewer is expected to adapt to the respondent while at the same time following the same procedure for every respondent. Also, standardization in interviews confuses standardization of questions with the standardization of meaning to the respondents. In responding to questions, the respondents are involved in a process of interpretation, implying that

an identically worded question may be administered to all respondents, but this does not guarantee that it has the same meaning for all respondents. Individuals have unique ways of defining their world and, to understand that world meaningfully, researchers must approach it from the subject's perspective. From the feminist perspective⁵⁵, for example, distortions and misunderstandings are particularly likely to arise in situations where the researchers' categories and language reflect a male perspective (DeVault & Gross, 2007).

In support of standardization is the fact that it can serve as antidote to bias and as a means to isolating respondents' true opinions from the distortion of response effects. The interviewer can be sure that any differences between respondents which are uncovered are attributable to real differences rather than to differences in the instrument or research procedures. The advocates of non-standardized approach recommend achieving 'equivalence of meaning' which would entail encouraging interviewers to tailor their questions to the vocabulary and understandings of individual respondents rather than imposing a uniform set of stimuli, which may be differently interpreted by different respondents. The interviewer and the respondent are seen to be 'talking together' rather than behaving as 'stimulus-sender and response-emitter' (Mannix, Wilkes, & Daly, 2015; Roulston, 2014). Thus, stimulating a real-life scenario with the advantage of clarity of expressions, and opportunities for probing questions to check meanings and add information. This is the goal of key informant interview. It allows for intimate contact with study participants. This method of enquiry encourages pursuit of details and locates the real in the 'world' of the respondent.

⁵⁵ The concept of feminism and feminist ethics is discussed in section 4.3.3, p. 77.

7.4.2 Focus groups

A focus group (FG) or focus interview is defined as a method of collecting research data through moderated group discussion based on the participants' perceptions and experience of a topic decided by the researcher (Bender & Ewbank, 1994; Kitzinger, 1995; Powell & Single, 1996). Historically, FGD originated in the work of the Bureau of Applied Social Research at Columbia University in the 1940s. Paul Lazarsfeld, a sociologist, led the study on commercial market research on audience responses to soap operas in response to the United State government request that the Bureau should assess the impact of its wartime radio propaganda on the population (Bloor, 2001). It can be used either as a stand-alone method for research relating to group norms, meanings or processes or as a multi-method design to explore a topic or collect group language. Simply put, it is employed within a multi-method research design to help: a) identify research foci or develop research question prior to the conduct of the main study (i.e. sequential mixed methodology approach); b) clarify, extend or qualify findings produced by other methods; and c) feedback of research findings to study participants (Bloor, 2001; Bloor, Frankland, Thomas, & Robson, 2001).

Focus group discussions create a context in which a topic can be explored in depth. The knowledge about the topic to be discussed should not be presumed. In focus group discussions, the point is to presume little or no knowledge to gauge study participants' understanding of, interest and perceived stake in, the topic of interest (Weir, Morin, Ries, & Castle, 2010). In effect, focus group discussions use information from literature reviews or other contextual knowledge to develop criteria for a judgment sample of participants. FGD involves a small number of participants and is not expected to be representative of the larger population. The small group, usually consisting of 6-8 individuals, sharing particular characteristics like age group, gender,

social class, geographic location or similar disease affectedness. The FGD encourages informal group discussions in a ‘focused’ manner around a particular topic or set of ‘issues’, often guided by scheduled questions under the moderation of the researcher.

The focus group is the unit of analysis in FGD studies hence the sample size refers to the number of groups and not the total number of participants in the study. It has been recommended that a minimum number of 4 and maximum number of 12 participants should comprise a group (Kitzinger, 1995; Bender et al, 1994; Stewart, Shamdasani & Rook, 2007). More importantly however is the emphasis that the strength of qualitative research lies in the ability to explore the depth and complexity of the phenomena under scrutiny. Therefore, quantity must be balanced against quality, and the more hours of taped interviews or pages of transcribed material, the less depth and richness the authors will be able to extract from the material (Morse, 2007).

7.4.3 Appraisal of methodology and Rationale for my data collection methods

One of the principal strengths of qualitative methods is the opportunity to gain in-depth insight of the perspectives and the meanings which inform the behaviours of my study participants (Murphy et al., 1998). Hence qualitative enquiry facilitated understanding of my phenomenon of interest holistically as it helped me to identify and interview groups of people who either possessed characteristics or live in circumstances relevant to the social phenomena I investigated so that I could generate relevant data to answer my research questions. This was particularly important for my thesis because the understanding of why individuals would choose to or not to give informed consent to participate in genomic research, and the reasons for acceptance of community engagement strategies gave a better appreciation of the participants’ values and, allowed for the respect of these values in the formulation of ethical guidelines for

genomic research in the region of my study. Therefore, I chose two qualitative methods, namely key informant (in-depth) interviews and focus group discussions (FGD).

For the in-depth interviews, I used the semi-structured type in which I verbally administered several key questions (prepared as an interview guide – Appendix iii, p.341) that not only defined the areas I explored, but also allowed me or my research participant (the interviewer or interviewee) to diverge in order to pursue an idea or response in more detail. This interview format, according to Gill et al, ‘is used most frequently in healthcare research, as it provides participants with some guidance on what to talk about, which many find helpful’ (Gill, Stewart, Treasure, & Chadwick, 2008; p.291). The flexibility of this approach allows for discovery or elaboration of information that is important to participants which I might not have previously thought of as pertinent. I did not choose a structured format because, though it is relatively quick and easy to administer, it limits participant responses and therefore of little use if ‘depth’ is required (Legard, Keegan, & Ward, 2003). Similarly, I did not choose unstructured format because it is time consuming and can be difficult to manage since it does not reflect any preconceived ideas or theories and is often performed with little or no organisation (Finlay & Ballinger, 2006; Natasha Mack et al., 2011; Oye, Sorensen, & Glasdam, 2015) thus providing little guidance on what to talk about which makes it difficult for the participant. As stated by Gill et al (2008: p 291), ‘their use is, therefore, generally only considered where virtually nothing is known about the subject area’ (Gill et al., 2008), which was not the case for my thesis.

Focus groups are more than just collecting similar data from many participants at once. It generates information on collective views and the meanings behind those views. Interaction is key to success of focus groups. I considered this in the categorization of my focus groups by setting up groups based on age brackets. This has been corroborated to be beneficial ‘as pre-

existing groups may be easier to recruit, have shared experiences and enjoy comfort and familiarity which facilitates discussion or the ability to challenge each other comfortably' (Bloor et al., 2001).

These two methods, that is interview and focus groups discussion, have their strengths and limitations. The application of both in qualitative research is complementary as the limitation of one can be addressed by the strength of the other. For example, focus groups are not the best method for acquiring information on highly personal or socially sensitive topics, key informant interviews are better suited for such. Conversely, focus groups enable stimulation of conversation using group dynamics and allows observation of reaction of participants, whereas in-depth interview is limited to individual experiences, opinions, and feelings.

Having discussed my methodological approach and rationale behind the choice of my data collection methods, it is important to describe how I ensured the quality of my data collection process and analysis before discussing the details of my research process.

7.5 Quality of data and analysis

In qualitative research, concerns about the credibility and dependability of findings, and transferability and reliability of normative conclusions with recommendations are paramount. Here, I specifically elaborate on the methods I applied to ascertain the credibility, dependability and transferability of my data and analysis.

On one hand, I ensured credibility by assessing my findings in several ways, including to what extent my findings cohered with what was already known and reasonably explained the phenomenon of interest, and how much attention I paid to alternative explanations or interpretations of findings to show rigor and completeness in my analysis. While on the other

hand, I ensured dependability by the degree to which I accounted for and describe the changing contexts and circumstances during my research. This was further enhanced by altering the data collection as new findings emerged. I used the following methods to ensure credibility and dependability: a) Triangulation, b) Code-recode/coder reliability, c) Reflexivity, d) Peer briefing and examination, and e) Deviant case analysis. I did not use participant validation because it is time consuming and requires extra financial commitments as it demands taking my findings back to the field for verification by the study participants. Furthermore, I ensured transferability and conformability of my research findings by using my a) reflective commentaries and b) research diary to create a ‘thick’ description of my data. First, I discuss how I used triangulation, and thereafter discuss the other methods.

- a. *Triangulation*: I employed informant and methodological triangulation for my thesis. For informant triangulation, I obtained qualitative data on the ethical issues of informed consent and community engagement processes from four groups of respondents, namely potential research participants, community leaders, community health workers, and biomedical researchers, explored their perceptions and probed for consensus or divergence in explanations to their views and experiences. For the methodological triangulation, I employed two methods for data collection, in-depth interviews and focus group discussions. I used the methodological and informant or data triangulation to gain different perspectives on consent process and community engagement in genomic research by comparing divergence and similarities between the findings from the different data sources and methods. This approach has been used by previous researchers (Fagbemi & Adebamowo, 2014; Kojuri et al., 2015; Shenton, 2004; Speziale & Carpenter, 2007; Wiig et al., 2014).

In addition, I used both within-method and between-methods approaches for the methodological triangulation of the focus groups and in-depth interviews (Jick, 1979; Speziale & Carpenter, 2007). The within-method involves comparison between responses from the four categories⁵⁶ of participants for FGD and three categories⁵⁷ of participants for in-depth interviews on different topics discussed, and comparison between the different ethical issues themselves which constitute phenomena of interests, with the aim of checking both data dependability and credibility of my research. In the between-method approach, I compared the responses obtained by the two different qualitative methods I used, that is FGDs and interviews. This ensured convergent and divergent validity, meaning I was able to detect similarity of responses on same ethical topics and divergent views on different ethical topics using different methods (Cataldi, 2016).

- b. *Code-recode reliability/coder reliability index*: I also employed this method to ensure credibility of my data and methods. I open-coded half of my data and after two weeks re-coded the same half, then compared the results of the two coding processes for similarities and differences. The agreement of the outcomes of the two mirrored dependability of my qualitative inquiry (Curry et al., 2009; Mays & Pope, 2000). Furthermore, I got a researcher to code twenty percent of my data using a similar coding frame I used and the outcome was compared with my coding outcome for coder reliability index (my coder reliability index was above 90 percent) which reflected the high degree of similarity of the two outcomes (Bergman & Coxon, 2005).

⁵⁶ The four categories of FGD included the adult males, adult females, male youths and female youths.

⁵⁷ The three categories interviewed included the community leaders (kings and community elders), community health workers and the biomedical researchers.

- c. *Reflexivity*: I employed reflexivity in my study from the outset. For example, I was careful to think about personal and intellectual biases in the selection of my study site and ensured non-disclosure of my professional status during my interaction with research participants in the field. I chose a research field far from my job site while in Nigeria to prevent any direct or indirect interference with participants' responses. Furthermore, I was sensitive to gendered and age effects on FGD outcome so I categorised the focus groups using gender and age, and while conducting FGD with the female groups I had a female co-moderator with me during the sessions, to facilitate an informal, tension-free atmosphere and continuous dialogue between participants. I was flexible with my participants' recruitment and data collection process, and allowed modifications based on emerging themes from my initial data (Darawsheh, 2014), so I constituted a mixed group of adult and youth participants to observe interaction between and obtain responses from them. This further contextually enriched my data, strengthened the outcome of my analysis, and 'placed confidence in the truth of my research findings' (Anney, 2014, p.276).
- d. *Peer briefing/examination*: I used this method to scrutinize my research protocol and topic guides before my fieldwork. My protocol and topic guides were reviewed by my supervisors for ambiguities, this allowed me to make necessary revisions before implementing my research.
- e. During my analysis, I ensured identification and analysis of *deviant or negative cases* thereby accounting for the contradiction emerging from my data and provided plausible alternative explanations for these phenomena. This improved the rigour and credibility of my study (Nicholas Mays & Pope, 1996; Parker, 2009).

- f. *Thick description of my research* was facilitated by my *research diaries and reflective commentaries* which I compiled while in the field. This allowed for detailed description of my data collection process from the development of my research protocol to applying for ethics approval, recruitment of study participants, the interview process and FG discussion sessions as well as incorporating the *audit trail of coding* from my analysis to facilitate dependability and transferability of my research (Anney, 2014; Seale, 1999).

7.6 The research process

In this section, I present a narrative account of my research process. This account describes the details of jottings from my research diary, including step-by-step implementation of my research protocol, exposition of data collection, challenges I confronted, and practical decisions I took with reasons for taking such decisions. This narrative account contributed to strengthening the validity or credibility of my research. Observations of what happens in the field during research can serve as useful primary source of data and assist in making the research process explicit so that readers can ‘trace the route by which you (*I*) came to your (*my*) interpretation’ (Mason, 1996: p.150)⁵⁸.

7.6.1 The main research

I am a medical graduate and neurology specialist but developed my keen interest in ethics of biomedical research a decade ago when I was confronted with ethical dilemmas while conducting research on improving health services for patients with epilepsy. It was during my search for solutions to my ethical challenges of how to tackle issues of confidentiality and risks (stigmatization of the patients) that I came across the Nigerian National Code of Health Research

⁵⁸ The italicized words are my additions to the quoted statement.

Ethics⁵⁹, a document I was not aware of before then. This prompted me to enlist for and complete a Master of Science (MSc) program in bioethics as a National Institute of Health Fogarty scholar. Subsequently I developed interests in research ethics and specifically in ethical conduct of research in developing countries. Getting to know that a national code was in existence without my knowledge as a biomedical researcher stimulated my Master's degree thesis in the development of an online module based on the national Code of Health Research Ethics. I designed and developed this online module for ethics education of foreign and indigenous biomedical researchers, and assessed its internal consistency as a measure of its reliability⁶⁰. I have sustained my interest in research ethics and ethics education, and this stimulated further closer and in-depth analysis of the national code, during this analysis I discovered that the code has several drawbacks and gaps, one of which is absence of ethical guidelines for conduct of genomic research in Nigeria.

This prompted my search for existence of ethical guidelines for genomic research in other sub-Saharan African countries, especially with the introduction of the H3Africa Initiative⁶¹. I discovered that there are no specific ethical guidelines for the conduct of genomic research in sub-Saharan Africa though a few countries like South Africa, Nigeria and Kenya have guidelines for transfer of human biological specimens. More importantly, there exist no guideline for what type of consent to obtain when conducting genomic research and how researchers could engage

⁵⁹ The Nigerian National Code of Health Research Ethics is a legal document formulated and adopted as guideline for ethical conduct of human subjects' research in Nigeria in 1987 but was signed into law in 2014 though it has become operational before then. It covers most ethical issues encountered in biomedical research but lack guidance on emerging innovations in biotechnology and genomics. Details of these have been discussed earlier in chapter three of this thesis.

⁶⁰ The outcome of this research has been published in BMC Medical Ethics 2013, 14:1

⁶¹ The H3Africa Initiative has as one of its goals the establishment of necessary research infrastructure to facilitate contemporary research approach to the study of genomics, and this has resulted in the establishment of biobanks in some African countries. Details on this initiative has been discussed on p.1 and section 2.3.4, p.21.

the participating communities especially considering the peculiar ethical issues encountered in this type of research. Therefore, instead of pursuing a doctorate research in neuroscience I chose to do research in biomedical ethics to address these gaps in conduct of genomic research in sub-Saharan Africa.

The main objective of my PhD thesis is to define how the interplay of communitarianism affect the informed consent process, and the dynamics and scope of community engagement in genomic research in Nigeria. To achieve my main objective, I sought to consider the following research questions, namely;

- a. What are the perceptions and opinions of indigenous potential research participants to participation in genomic research?
- b. What are the perceptions and views of indigenous potential research participants to ownership, storage, export, and future uses of their donated samples?
- c. What roles do community rulers, community opinion leaders, and family heads play in consenting to participation in genomic research?
- d. How do biomedical researchers perceive and understand community consultation and informed consent process in genomic research?
- e. Can the findings of this research contribute to development of ethical guidelines and policy for successful implementation of genomic research?

I developed my research protocol and applied to the Research Ethics Committee of the Lagos University Teaching Hospital Nigeria (since the study site is in Nigeria and this institution is in the same geo-political zone as my study site in compliance with the requirement of the Nigerian

National Code of Health Research Ethics⁶²) and the University of Liverpool Ethics Committee for ethics approval. I received approval from both Ethics Committees (see Appendices i and ii, pp.334-335).

7.6.2 Sampling

In conducting research, one of the key issues to address is who will constitute the participants. For my research, I had to make this decision at three-levels. First is to decide which developing country in sub-Saharan Africa could serve as my study site, and second which part of the country would be well suited for my study, and lastly which categories of individuals would serve as my study participants. I chose to conduct my research in Nigeria because it is one of the countries participating in the H3Africa project with new biobanks set up for genomic research and being a Nigerian, I am familiar with the topography and languages. My interest was in stakeholders directly involved with the consent and community engagement processes, and these include potential research participants (who have to consent to participate), community leaders who serve as custodians of community cultural norms (who may influence decision to participate and recruitment of the community members), and biomedical researchers (who have to administer the consent process and engage the participating community).

To accomplish this, I chose my site and samples purposively which is an acceptable method for qualitative research, as ‘samples are likely to be chosen in a deliberate manner, that will yield the most relevant and plentiful data given the study topic’(Kin, 2011; p.88). Therefore, a study site that would afford me access to scientists who are actively engaged in biomedical (including genomic) research involving human participants, and a well-defined community with

⁶² The Nigerian National Code allows for HREC to review and approve proposals for research that will be implemented in the same state or geo-political zone as the HREC – Section C, sub-section f (1,2)

identifiable cultural norms and practice was chosen. I used a theoretical sampling approach rather than aiming for a representative sample, to sample interviewees and focus group discussants until the categories reached theoretical saturation in order to ‘make key comparisons and test developing theoretical propositions’ (Mason, 1996; p.93). Next, I discuss theoretical sampling to explain what it involves, and thereafter give details of my study site and characteristics of my study participants.

Theoretical sampling is the process of data collection for generating theory whereby the researcher or analyst simultaneously collects, codes, and analyzes his/her data and decides what data to collect next and where to find them, in order to develop his/her theory as it emerges. This process of data collection is controlled by the emerging theory. In grounded theory, theoretical sampling is part of the progressive stages of the analysis since the theory is emerging as it is being systematically built out of the data. The first decision made about sampling is about the group or setting to be studied, while the second is about who or what to study within those groups or settings – ‘sampling within the case’ as demonstrated by steps taken in my study.

Sampling occurs along three major dimensions, namely; time, people (member-identified or observer-identified categories) and context. Member-identified category refers to folk categories as employed by members themselves, while observer-identified categories are developed inductively by the researcher based on his or her observations. Such sampling throughout the life of the research is referred to as sequential sampling or recursive sampling. The adequacy of within case sampling is an important strategy for achieving content validity in qualitative research (Seale, 1999).

The goal for sampling in qualitative studies is not to construct a sample that mirrors major demographic features of the target population, but rather to identify key informants with unique

experiences and personal knowledge of the phenomenon in question who can provide useful descriptions, insights and explanations of events relevant to the research questions (Kolopack et al., 2015). The criterion for judging when to stop sampling the different groups pertinent to a category is the category's theoretical saturation. Saturation means that no additional data are being found whereby I can develop properties of the category. In this context, when I observed similar instances over and over again, then I became empirically confident that a category was saturated. Therefore, I used a sampling technique in which new observations are selected to pursue analytically relevant distinctions rather than to establish the frequency or distribution of phenomena.

7.6.3 Study site

My study site is in Nigeria, a developing sub-Saharan west African country, situated in the Gulf of Guinea between Benin Republic and Cameroon with an estimated population of 186,053,386 people (July 2016) thus Africa's most populous country. It is composed of more than 250 ethnic groups but the most populous are Hausa and Fulani (29%), Yoruba (21%) and Igbo (18%). The official language in the country is English but there are over 500 additional indigenous languages, and religious affiliations are Muslims (50%), Christians (40%) or African traditionalists (10%) (CIA World Factbook, 2016).

Nigeria has experienced a rise in participation in genomic research which has resulted in the establishment of two bio-banks, one in Lagos (the commercial capital of the country) and one in Abuja, the federal capital territory. These developments necessitated the need for an understanding of communities' and potential research participants' perceptions of and attitudes to genomic research (i.e. whether they would be willing to participate in such research), the preparedness of Research Ethics Committees to review genomic research protocols and how

biomedical researchers can effectively engage the Nigerian communities in genomic research. The outcome of these enquiries may serve as a template for the development of ethical guidelines for genomic research in the country which can be incorporated into the existing Nigerian National Code of Health Research Ethics.

The specific study site is a tertiary medical/research institution situated in the south west geo-political region of Nigeria, the Ben Carson School of Medicine health facility, the medical school of Babcock University. It is situated at Ilishan Remo, a sub-urban area located between the cities of Lagos and Ibadan. It is a major town along the trade routes between ports in the Niger delta and the Yoruba mainland. The south-west geo-political region is inhabited predominantly by Yoruba speaking people who practice one of three types of religion; Christianity, Islam or African traditional religion. The population of the zone is 36 million representing 21% of the Nigerian population of approximately 170 million as at 2012 (CIA World Factbook, 2013). Around 40 million individuals throughout West Africa self-identify as Yoruba. This makes the Yorubas one of the largest ethnic groups in Africa. The urban population constitutes approximately 50% with an annual rate of urbanization estimated at 3.5% (CIA World Factbook, 2016). The migration pattern has resulted in mixture of the major and minor ethnic groups in major cities within the region with significant representation of the major religious groups thus making the region suitable for evaluating the impact of culture (religious beliefs, ethnic norms, etc.) on decision making in research participation.

7.6.4 Sample categories

My sampling was guided by a purposeful theoretical sampling strategy as earlier stated. The study participants comprised the following:

- a. Two community rulers and two opinion leaders, from the community in which the institution is situated, who participated in the in-depth interview (face-to-face, semi-structured interviews),
- b. Two community health workers who were recruited reflexively during the study as ‘member-identified’ category based on responses obtained from biomedical researchers during the interview process,
- c. Fifty community members (potential research participants) recruited from the medical/research institution and participated in Focus Group Discussions (FGD). They were divided into four categories and a mixed group constituted to probe emerging themes; the four categories include male adults (FGD1), female adults (FGD2), female youths (FGD3) and male youths (FGD4) - these different categories participated in different FGD sessions. Youths are young people between the ages of 18 and 30 years who are either married or unmarried. The cut-off age of 30 years was selected based on national youth policy. Individuals less than 18 years of age (considered as minors) were excluded from study because they are not involved in decision making as it relates to consent process in research within the Nigerian setting.
- d. Thirty biomedical researchers engaged in human subjects’ research at the research institution situated in the selected community participated in key informant (in-depth) semi-structured interviews.

7.6.5 Inclusion and Exclusion criteria

I employed inclusion and exclusion criteria not for selection of study participants but to ensure that individuals not from my study site are excluded from my study since such individuals may have different socio-cultural characteristics as distinct from my potential study participants.

Also, the criteria ensure ethical conduct of my research as lack of consent indicates exclusion from the study.

The criteria for participation in the study include: a) Membership of the community where study will be conducted, b) Provision of written or verbal (with thumb printing) informed consent, c) Ability to understand English and/or Yoruba language, and d) Availability to participate in FGD and/or interview session. The exclusion criteria were: a) Non-membership of the communities where study will be conducted, b) Failure to give informed consent, c) Non-availability to participate in FGD and interview sessions, d) Individuals less than 18 years of age, and e) Presence of mental or speech disabilities (which will be determined by the study investigator through mental state examination of the potential study participants. As the study investigator, I am trained to conduct this examination).

Prior to preparation of my study site and recruitment of research participants, I prepared and discussed my interview and FGD topic guides with my supervisors, who scrutinized and made suggestions to improve them, then I conducted a pilot study. I briefly discuss my topic guides and pilot study before describing the data collection process on the field.

I developed my topic guides from previous literature⁶³ on ethical issues encountered in genomic research and normative reasoning based on basic ethical principles.

⁶³ I conducted a systematic review of ethical issues peculiar to genomic research using two databases; PubMed and Internet search with Google. I used the following search terms: genomic research AND 'ethics' AND 'ethical guidelines' AND 'biobanking' AND 'informed consent' AND 'community engagement or community participation or community-based participatory research or community-engaged research' AND 'developing countries or Africa or sub-Saharan Africa). Only documents which address the ethical concerns or challenges encountered in genomic research were reviewed.

Interview topic guide (see Appendix iii, p.341): For the Key Informant Interview, the questions that guided the process were based on the following issues:

- a. Demographic data of the study participants (Harris, Parrott, & Dorgan, 2004)
- b. Knowledge of genetic and genomic research
- c. Particularities of ethics in research in their communities
- d. Process of decision making in their communities
- e. Awareness of benefits and risks of research,
- f. How their cultural and religious beliefs impact on research participation,
- g. What they know and understand by informed consent and who gives the consent,
- h. How do they view export of donated specimens, ownership of such specimens and desirability for feedback following analysis of specimens, and
- i. Awareness and adequacy of the national code of health research ethics in conduct of genetic and genomic research.

Discussion topic guide (see Appendix iv, p. 345): For the focus group discussions, the questions that served as my guide during the process were based on the following:

- a. Demographic data of the study participants to include gender, level of income, ethnic orientation, religious affiliation, age and level of education (Harris, Parrott, & Dorgan, 2004)
- b. Knowledge of genetic and genomic research
- c. Particularities of ethics in research in their communities
- d. Process of decision making in their communities
- e. Awareness of benefits and risks of research,

- f. How their cultural and religious beliefs impact on research participation (Tindana, Molyneux, Bull, & Parker, 2014),
- g. What they know and understand by informed consent and who gives the consent (Tindana et al., 2012),
- h. Views on the export of donated specimens, ownership of such specimens and desirability for feedback following specimen analysis

7.6.6 Pilot study

In January 2016, two months before travelling to the field for my research, I conducted a pilot study among a small convenience sample of two postgraduate students and six undergraduate students of the University of Liverpool. I approached eight participants from a group of students engaged in a joint social group and asked for their consent to participate. I discussed details of my research, what I expected of them and gave them the participant's information sheet to read (appendix v, p.348). I gave them opportunity to ask questions about the research before obtaining their verbal consent. I made it clear to them that they were participating in a pilot study.

I interviewed the two postgraduate students and conducted two focus group discussions with three undergraduate students in each group. I chose to interview the postgraduate students because their tertiary level of education was comparable to that of the biomedical researchers who would be interviewed on the field. The first and second interviews lasted one hour 17 minutes and one hour 5 minutes respectively. The focus group discussions lasted one hour per session. Apart from obtaining the responses of the participants during the interviews and observing the interaction between the focus group discussants, my primary goal was to seek their understanding of the questions and the phenomena of interest.

I used the outcome of my pilot study to ascertain the reliability of my questions by ensuring consistency of the responses between the two interview respondents, and the pattern of responses during the two focus group discussions. This gave me insight into whether my respondents on the research field would understand how my questions were framed and the key terminologies used in my topic guides, thus helping me to test and refine my approach. In other words, it provided me with an ‘opportunity to practice’ (Kin, 2011: p.35). Also, it has been noted that ‘during the process of constructing the research question and the associated instruments, the importance of pilot studies in close collaboration with members of the study population cannot be overemphasized’ (Bergman & Coxon, 2005: p.5). I obtained information on logistics, for example, I learned about the likely field time needed to cover my interviews and FGDs. I modified my questions and topic guides after the pilot study to achieve my desired goal of clarity of presentation. In addition, I observed the likely pattern of probes that might be necessary for my fieldwork. The use of probes implied a construction of meaning during the interview process, as they are based on ad-hoc analysis of the content of the response of the participants.

7.6.7 Community entry and preparation of the field

To facilitate a smooth launch and progress of my research, I did the following:

- a. I made a first ‘fact-finding’ trip to Nigeria to identify and assess the suitability of my research field, collect relevant logistic information like proximity of research institution to the community, and accommodation during my stay for the period of my research
- b. I identified and established a contact person in the research institution situated in the community (observer-identified category⁶⁴)

⁶⁴ Observer-identified category is inductively developed by the researcher. Details discussed under Theoretical Sampling above

- c. I contacted and received permission to proceed with my research from the institution's authority
- d. I established contact with the Ikenne Local Government Area (LGA) authority through a community health physician and a community health nurse working with the institution (observer-identified category)
- e. I contacted the community health workers in the LGA's health office, who in turn assisted in establishing contact with community opinion leaders (member-identified category⁶⁵)
- f. I contacted the community rulers through one of the community opinion leaders (member-identified category)
- g. Contacted the biomedical researchers through my institution's contact (member-identified category) See flow chart – Figure 4.

7.6.8 Recruitment process

I initiated the recruitment process with the help of my contact at the research institution. I obtained a written permission from the head of the institution to proceed with my research after my protocol and ethics approval certificates were scrutinized and confirmed authentic (see appendix vi, p.350). I commenced recruitment and the interview process with the biomedical researchers. They were adequately informed of details of research and given opportunity to ask questions before obtaining their consent.

As the interview and iterative analysis of the data progressed, I observed that one of the respondents alluded to the role played by community health workers from his previous research experience, so I incorporated the community health workers into my research participants'

⁶⁵ Member-identified category is employed by the community members, members of this category are identified by individuals within the community. Details discussed under Theoretical sampling above

categories. I visited the Ikenne Local Government area (LGA) headquarters, the secretariat of the community, where I was introduced to the leader of the Community health office and the community health workers. The community health office (CHO), situated in the local government area secretariat, is concerned with implementation of public health policies, namely child health care, maternity services for women, environmental sanitation and prevention of common diseases like malaria, diarrheas and polio, at the community level. With the assistance of the leader of the community health office, I was introduced to the community health workers. The community opinion leaders were identified and contacted through the community health workers. One of the community opinion leaders took me to the community rulers of the two communities within the local government area who agreed to be interviewed. The community leaders and health workers were recruited after they were adequately informed of what the research is about, or if literate given the information sheet to read, and opportunity to clarify issues relating to the research.

The FGD participants were approached personally and through a hospital contact when they registered at the institution's medical records department. Prior to recruitment, I informed the participants of details of the research, and other necessary information which included name and address of investigator, purpose of research, duration of research, what is expected of participants, possible risks and benefits, the fact that they can withdraw from research at any time during the research without compromising their rights, any inducement or compensation, and their voluntary informed consents were obtained. For those who were literate and could read, I gave them the information sheet to study and opportunity to ask questions about the research (appendix v, p.348). For those who could not read, I personally gave them the details of what the research entailed emphasizing the fact that they were under no obligation to participate and they

could withdraw from the research at any time without consequence. Also, I gave them opportunity to ask questions.

All the study participants were recruited after they gave their consent. Consents were obtained written either in form of signature or thumb printing (appendix vii, p.351). Verbal consent was accepted in situation where the participant is uneducated (that is cannot read and write) and choose to give such. As much as possible, the recruitment was done at the first contact as it is more difficult to follow up and get the potential participant to consent subsequently. Refer flow chart – Figure 5.

7.7 Methods

I elaborate on how I conducted my interviews and focus group discussions in this section, what compensations were given to the study participants, and how I ensured theoretical saturation.

7.7.1 Interview process

I started my interviews with the biomedical researchers as earlier stated. I received a cordial and warm reception from the researchers having been introduced to them by my institution's contact who is a colleague of theirs during the recruitment phase. I arranged date and time of interview with each of them. On the day of interview, I introduced myself (without details of my professional status or academic background)⁶⁶ and the purpose of the interview. I emphasized that there are no right or wrong answers, rather the goal was to obtain their honest views, opinions and experiences on issues relating to informed consent and dynamics of community engagement in genomic research. Information on genomics was not provided in

⁶⁶ Details of my academic and professional background are stated in section 7.6.1, p. 155.

advance of the interview so that researchers' knowledge of this area could be ascertained. I used my interview topic guide, but I did not restrict my approach to the guide alone as I allowed the interview to flow as each interviewee gave answers to each question. I encouraged the interviewees to share their experiences from previous research they have conducted and other relevant life experiences. The interview process for the researchers lasted two weeks. I interviewed between two and four participants a day, each interview lasting between 45 minutes and one hour ten minutes. The interviews were tape recorded and transcribed verbatim daily into text. I imported the transcripts into Atlas.ti and carried out the initial coding of the data using my coding frame (see Appendix viii, p. 354). During the process of interacting with my data and initial coding, I identified areas that needed further clarification and probing, and these guided me in subsequent interviews.

In the same way, I arranged time and place of interview with the two community opinion leaders. The interviews took place in their respective houses within the community on different days. I introduced myself, purpose and details of my research. I made them appreciate the fact that there are no right or wrong answers, rather they should be at liberty to share their views, opinions and experiences in their answers to the questions. The first and second interviews lasted 55 minutes and 68 minutes respectively. The interviews were tape recorded and later transcribed into text and imported into Atlas.ti as done for the biomedical researchers. I sought the views, opinions and perspectives of the two community rulers on the consent process acceptable to the community against the socio-cultural background of the community, as well as their expectations of engagement strategies by researchers. The interviews held on two separate days of the week in their respective royal palaces. The first interview held in the company of two community chiefs

and lasted 60 minutes, while the second interview was with the community ruler only and lasted 40 minutes. The interviews were tape recorded and transcribed as done with other interviews.

Lastly, I interviewed two community health officers, one in charge of the malaria eradication program and the other maternal and child health. They have assisted researchers to engage the community in the past and were willing to express their views and share their experiences. I gave them the information sheet to read, opportunity to ask questions about my research, and then obtained their consent. Each interview lasted for 40 minutes.

7.7.2 Focus group discussions

I conducted the focus group discussions with four or six participants at a time, based on the four categories earlier stated. My choice of four or six participants per group was based on Fern (1982) who opined that more information is obtained by conducting two groups of four participants than one group of eight participants (Fern, 1982). Also, Morgan reported that most qualitative studies used four to six groups before reaching saturation provided the questions are standardized and the participants' categories are limited (Morgan, 1996).

The first FGD was with the adult females, then the adult males followed by the female youths and the male youths. All the FGDs held in a quiet, well-lit room within the institution. All participants had earlier agreed to a convenient time, in the morning hours, and I made arrangement to convey those who had challenges with transportation. I had a female co-moderator, a staff member of the Medical Records department of the institution who is from and familiar with the community, with me for the female sessions. I did the initial introduction and then allowed her to moderate while I took notes, only interjecting when there was need to clarify any issue of interest. This created a friendly and tension-free atmosphere for free and unhindered

flow of dialogue among participants. I moderated the male FGDs alone, but had one assistant (a Master graduate in Sociology) for all the sessions who took notes.

Before each session started, all respondents were given a brief explanation of purpose of the FGD and asked to express what they understand about genomic research and thereafter I defined what genomic research is to establish a common starting point (see Appendix ix, p.358). A cordial and relaxed atmosphere was created, and participants were encouraged to express their views, opinions and experiences on the topics discussed. The discussions and interaction between group members were tape recorded. Each FGD session lasted for a period of 45 minutes to one hour. All the sessions were tape recorded and they agreed to this as part of the consent process, and notes were taken by my assistant to supplement the recording. The notes were compared with the transcribed texts from audio-recorded FGDs. The data obtained were transcribed verbatim daily after each FGD for analysis.

I chose to have separate groups for the males and females to prevent gender-related authority influence and impact of religious sensitivities on their group interaction. This categorisation of participants will prevent paternalism which is prevalent in some Nigerian cultures and this affects women and young persons from freely expressing themselves in a mixed group as noted previously by Fagbemi *et al* (Fagbemi & Adebamowo, 2014). The adult males, who are regarded as family heads, are believed to take health-related decisions for their wives and children (Agulanna, 2008; Kritz, Makinwa-Adebusoye, & Du, 1995; Tessaro, Borstelmann, Regan, Rimer, & Winer, 1997). In the traditional African setting the married women are expected to not only discuss research participation and acceptance or refusal of medical treatment with their husbands but, comply with the decision of their spouses (Marshall *et*

al., 2014). So, I expected the views of the family heads to shed light on why and how they arrived at decisions, and on the process undertaken to engage their spouses in decision making if any.

The women were in a separate FGD category to allow freedom of expression among the group members with the objective of developing a deeper understanding of gender inequalities within the family setting and community, and how these affect the community engagement process. The women were encouraged to talk about this during the focus group discussion sessions. I observed from my review of the literature that the youths were seldom included as participants in most qualitative studies on research participation conducted in sub-Saharan Africa despite their potentials for engaging in empirical studies. From my stand-point, I thought that it should not be assumed that the opinions of youths were like that of the other groups within the same community, therefore, to ignore their contribution to the research process, especially community engagement, is to create unstable dynamics in the community-based participatory structure of research design. This was the rationale for including two focus groups categories, male and female FGDs for the youths in my study.

In summary, for this study, I determined the number of focus groups by 'point of saturation' based on the grounded theory described by Glaser and Strauss (1967) as earlier stated on page 146. In this approach, I conducted FGD with different categories of informants selected by purposive sampling and the data collection i.e. recruiting, interviewing and analysis, as an iterative process for each FGD. This was done until saturation point was reached for each category of informants i.e. no new or relevant data seem to emerge regarding a category. For my research, I had 15 FGD sessions comprised of three sessions for adult males, three sessions for adult females, four sessions for male youths, four for female youths, and a session of a mixed

group of three adults and three youths to probe contrasting viewpoints between the adult and youth participants⁶⁷. I made two trips to the research field to achieve saturation.

7.7.3 Special arrangements for potential study participants

Unfortunately, the onset of my research coincided with scarcity of fuel in Nigeria and this made transportation problematic. Therefore, I made special transport arrangements to convey study participants from a pre-arranged location in the community to the research facility for focus group discussions. The biomedical researchers transported themselves to work and were interviewed in their various offices, and on few occasions in the office of my institution's contact, based on their convenience.

7.7.4 Compensation of study participants

The participants were compensated with refreshments (snacks and soft drinks). They were offered common non-sugary soft drinks and snacks after the FGD sessions or interviews. In addition, those who opted to return to their destinations by themselves after the FGD or interview sessions were offered transport fares at the current prevailing rate. In addition, I offered the biomedical researchers free copies of the Nigerian National Code of Health Research Ethics and information on online bioethics resources for ethics education.

7.7.5 Second research trip to ensure theoretical saturation and debriefing

For the purpose of ensuring theoretical saturation, I undertook a second trip to the research site to conduct additional FG sessions with community members to clarify any issues until saturation point was reached (Chenitz & Swanson, 1986; Thornberg, 2012; Thornberg & Charmaz, 2014). I eventually achieved theoretical saturation after 15 FGD sessions, including the session with the mixed group of adults and youths. I recruited the participants using the similar

⁶⁷ The details of my study participants are presented in the next chapter, Tables 4 and 5; pgs. 180, 183

procedures I used with the participants during the first trip. In addition, at the end of my data collection I conducted two sessions of debriefing with ten biomedical researchers and fifteen community members who participated in my research (appendix x, p.359).

7.7.6 Ethical Considerations

Before the commencement of my study I submitted my research protocol first to an institutional REC in Nigeria for approval, then to University of Liverpool REC. The study protocol was approved by the Research Ethics Committee of the Lagos University Teaching Hospital Nigeria (Reference number ADM/DCST/HREC/1792; appendix i, p.339) and Institutional Research Ethics Committee of the University of Liverpool (Reference number IPHS-1415-LB-270; appendix ii, p.340). Written informed consent was obtained from all study participants (appendix vii, p.351), and verbal informed consent (with evidence of thumb printing) from participants who are not literate. Consent was also obtained for audio recording of the interviews and focus group discussions. Data obtained were de-identified to ensure participants' privacy and maintenance of confidentiality in accordance with principle of respect of persons. I used pseudonyms to identify participants for reason of confidentiality. Data were stored on my institutional M drive in a private laptop which was password-protected.

Figure 4 FLOW CHART OF STUDY PROCEDURE

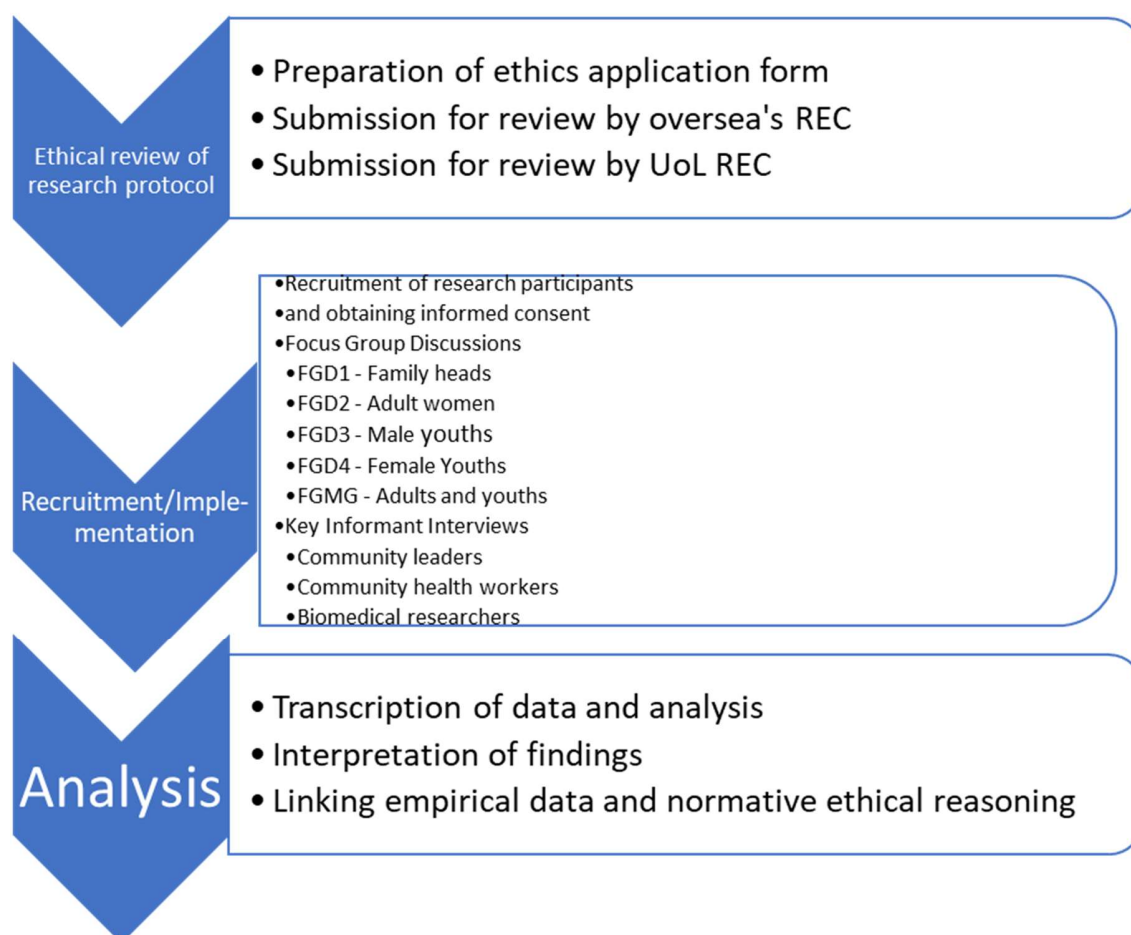
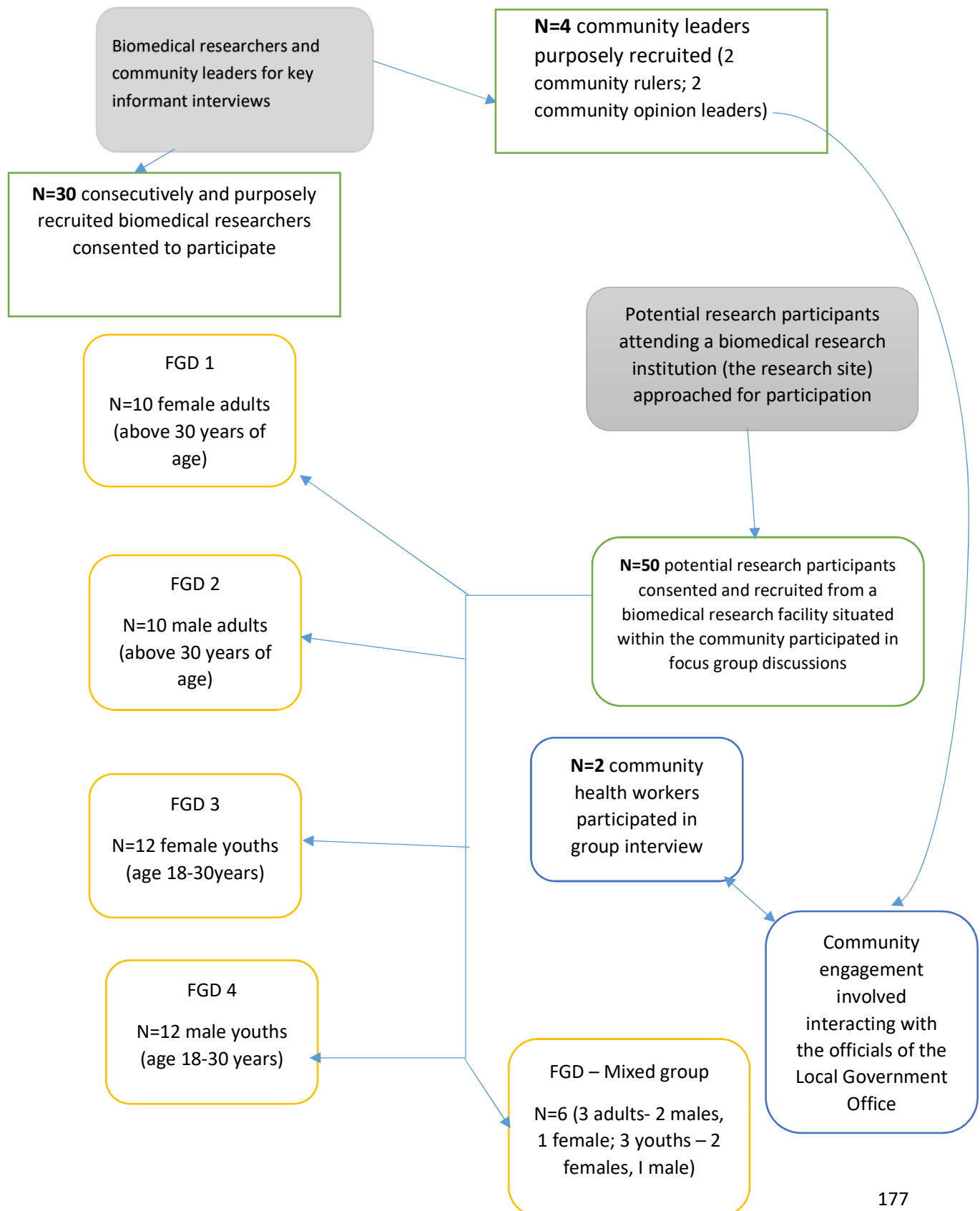


Figure 5 RECRUITMENT PROCESS – FLOW CHART



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PART III

THE DATA

CHAPTER 8

RESULTS OF DATA ANALYSIS

8.1 Introduction

This part of my thesis comprises the discussion of my data. But first I present the demographics of my study participants, discuss the approach I chose for the discussion of my data and the reasons for choosing this approach.

8.2 Study participants

There are two main categories of participants, namely the community members and the biomedical researchers (in a health facility situated within the community). The community members were further divided into three sub-categories; the community leaders comprising the king and community elders (constituting the community authority structure), the community health workers, and the community people or individuals who constitute potential research participants.

8.2.1 Biomedical researchers

I interviewed 30 biomedical researchers, comprising 16 males and 14 females, with a mean age of 40.4 (SD 5.4) years and age range of 33 to 56 years. Most of them were involved in clinical science research, only three engaged in laboratory-based genetic studies. All but 2 were Yoruba. Details of the demographics are presented in Tables 3 and 4.

Table 3 Summary of demographics of biomedical researchers

Summary of demographics

| | | Frequency | |
|--------------------|-------------------|----------------------|---------------------|
| Age distribution | Male | | Male |
| | 31-40 years | 8 | Mean: 42.4 (SD 6.2) |
| | 41-50 years | 6 | Median: 40.5 |
| | 51-60 years | 2 | Range: 35-56 years |
| | Female | | Female |
| | 31-40 years | 11 | Mean: 37.5 (SD 3.1) |
| | 41-50 years | 3 | Median: 38 |
| | 51-60 years | 0 | Range: 33-43 |
| | Total | | Total |
| | 31-40 years | 19 | Mean: 40.4 (SD 5.4) |
| Sex distribution | Male | 16 | |
| | Female | 14 | |
| Level of education | Primary | - | |
| | Secondary | - | |
| | Tertiary | - | |
| | Postgraduate | 30 | |
| Area of research | Basic sciences | 8 | |
| | Clinical sciences | 19 | |
| | Genomic research | 3 (Laboratory-based) | |
| Ethnicity | Yoruba | 28 | |
| | Igbo | 2 | |

Table 4 Details of demographics of biomedical researchers

| <i>Serials</i> | <i>Sex</i> | <i>Age</i> | <i>Area of research</i> |
|-----------------------|-------------------|-------------------|--------------------------------|
| Dr Susan | F | 37 | Paediatric |
| Dr Sugar | F | 38 | Ophthalmology |
| Dr Max | M | 42 | Psychiatry |
| Dr Sandy | F | 40 | Ophthalmology |
| Dr Matt | M | 51 | Microbiology |
| Dr Steel | F | 40 | Renal Medicine |
| Dr Monty | M | 35 | Cardiology |
| Dr Mendy | M | 45 | Community Health |
| Dr Mouldy | M | 41 | Microbiology |
| Dr Stephanie | F | 35 | Surgery |
| Dr Stone | F | 41 | Community Health |
| Dr Mole | M | 37 | Surgery/Urology |
| Dr Shaw | F | 38 | Neurology |
| Dr Sharp | F | 42 | Chemical Pathology |
| Dr Mills | M | 49 | Radiology |
| Dr Shade | F | 34 | Cardiology |
| Dr Soul | F | 33 | Cardiology |
| Dr Saint | F | 40 | Endocrinology |
| Dr Martin | M | 37 | Pathology |
| Dr Munchy | M | 38 | HIV/AIDS |
| Dr Sunny | F | 43 | Renal Medicine |
| Dr Mellow | M | 50 | Laboratory (Genetic) |
| Dr March | M | 38 | Haematology |
| Dr Mark | M | 56 | Radiology |
| Dr Moon | M | 44 | Laboratory (Genetic) |
| Dr Song | F | 36 | Community Health |
| Dr Meadows | M | 37 | Paediatrics |
| Dr Misty | M | 39 | Pulmonology |
| Dr Stuber | F | 35 | Cardiology |
| Dr Mentor | M | 40 | Laboratory (Genetic) |

8.2.2 Potential research participants (Community members)

I interviewed six community members (refer figure 6) and conducted 15 FGD sessions among 50 participants. Two community rulers and two community opinion leaders (including one who is a traditional medical practitioner) were interviewed. The demographics of the community rulers were not given as it is the customary practice not to divulge the King's age but they were males. I interviewed a 60-year old male and a 54-year old female who were opinion leaders (an opinion leader is a community member recognized by the local government authority to advise on community development issues). Also, I interviewed two female community health workers, 47 and 52 years of age. All these interviewees have Yoruba ethnicity and resided within the community.

Figure 6 Key Informant Interviews of community leaders

Four community leaders (including 1 who is a traditional health provider) and two community health workers comprising:

a. 2 community rulers

Males; Ages – not disclosed, Level of income – not disclosed

b. 2 community leaders/opinion leaders

One female; one male (traditional herbalist), F (54 years); M (60 years)

c. 2 community health workers

Females; Ages – 47 and 52 years, Ethnicity – Yorubas

FGD participants: Fifty community members participated in the focus group discussions, spread over 15 FGD sessions, comprising 24 females and 26 males. The FGD1 and FGD2 constituted the adult groups, while the FGD3 and FGD4 the youth groups. The FGMG (mixed group),

comprising of six participants; three adults and three youths, which was not predetermined at research outset but constituted during the research as a reflexive attempt to ensure saturation and credibility of my data analysis, probe an emerging theme. The details of their demographics are presented in Table 5.

The main objective of my research was in two parts. Firstly, was to explore and describe the roles played by community stakeholders in, and what were the perceptions of biomedical researchers to, community participation and informed consent process in genomic research. And secondly to explore what informs the decisions made by potential research participants on genomic research participation, specifically on donation of human biological samples for biobanking, and how the interplay of communitarianism and cultural practices affect their consent. In this part of my thesis, I present the discussion on my data.

While contemplating how I should discuss my data, I realized that there are two main approaches to writing up findings in qualitative research. The first is to simply report key findings under each main theme or category using appropriate verbatim quotes to illustrate the findings, and this is then accompanied by a separate discussion chapter in which the findings are discussed in relation to the extant research. This approach is identical to conventions in quantitative study reporting. The second approach is like the first but here the discussion is incorporated into the findings. I chose the second approach because I believed it offered me the advantage of clarity as well as robust presentation of my findings.

Table 5 Details of demographics of FGD participants

| FGD1a: Adult Female Group (31 years and above) | | | | | |
|---|----------------------|------------|---------------------------|-------------------|---------------------------|
| <i>Serials</i> | <i>Sex/Ethnicity</i> | <i>Age</i> | <i>Level of education</i> | <i>Occupation</i> | <i>Level of income/yr</i> |
| Mary | F/Yoruba | 52 | Primary | Trading | 50,000NGN |
| Elizabeth | F/Yoruba | 50 | Primary | Businesswoman | 90,000NGN |
| Flora | F/Yoruba | 58 | Secondary | Pensioner | Nil |
| Eugenia | F/Yoruba | 42 | Home tutoring | Businesswoman | 75,000NGN |
| Charlotte | F/ Igbo | 47 | Tertiary | Civil servant | 250,000NGN |
| Clara | F/Yoruba | 36 | Primary | Housewife | Nil |
| FGD2a: Adult Male Group (31 years and above) | | | | | |
| <i>Serials</i> | <i>Sex/Ethnicity</i> | <i>Age</i> | <i>Level of education</i> | <i>Occupation</i> | <i>Level of income</i> |
| Barnaby | M/Yoruba | 64 | Secondary | Pensioner | Nil |
| Baylor | M/Yoruba | 35 | Primary | Businessman | 80,000NGN |
| Taylor | M/Igbo | 55 | Tertiary | Clergy | Not specified |
| Philemon | M/Yoruba | 48 | Secondary | Businessman | 100,000NGN |
| Silas | M/Ndakwa | 52 | Secondary | Trader | 35,000NGN |
| Mackie | M/Yoruba | 60 | Primary | Pensioner | Nil |
| FGD3a: Youth Female Group (18-30 years) | | | | | |
| <i>Serials</i> | <i>Sex/Ethnicity</i> | <i>Age</i> | <i>Level of education</i> | <i>Occupation</i> | <i>Level of income</i> |
| Linda | F/Igbo | 29 | Tertiary | Business | 50,000NGN |
| Jane | F/Yoruba | 19 | Secondary | Student | Nil |
| Anne | F/Yoruba | 22 | Tertiary | Student | Nil |
| Hannah | F/Igbo | 28 | Secondary | Office assistant | 40,000NGN |
| FGD4a: Youth Male Group (18-30 years) | | | | | |
| <i>Serials</i> | <i>Sex/Ethnicity</i> | <i>Age</i> | <i>Level of education</i> | <i>Occupation</i> | <i>Level of income</i> |
| Darren | M/Yoruba | 27 | Secondary | Clerical staff | 60,000NGN/yr |
| Dillon | M/Yoruba | 26 | Tertiary | Student | Nil |
| Wood | M/Igbo | 23 | Tertiary | Applicant | Nil |
| Holmes | M/Yoruba | 20 | Secondary | Student | Nil |

| FGD1b: Adult Female Group (31 years and above) | | | | | |
|---|----------------------|------------|---------------------------|-------------------|---------------------------|
| <i>Serials</i> | <i>Sex/Ethnicity</i> | <i>Age</i> | <i>Level of education</i> | <i>Occupation</i> | <i>Level of income/yr</i> |
| Delilah | F/Yoruba | 41 | Nil education | Housewife | 40,000NGN |
| Dorcas | F/Yoruba | 38 | Primary | Trading | 90,000NGN |
| Deborah | F/Yoruba | 52 | Primary | Trading | 60,000NGN |
| Diana | F/Yoruba | 40 | Tertiary | Businesswoman | 125,000NGN |
| FGD2b: Adult Male Group (31 years and above) | | | | | |
| <i>Serials</i> | <i>Sex/Ethnicity</i> | <i>Age</i> | <i>Level of education</i> | <i>Occupation</i> | <i>Level of income/yr</i> |
| Williams | M/Yoruba | 56 | Primary | Trading | 120,000NGN |
| Warren | M/Yoruba | 40 | Tertiary | Civil service | 380,000NGN |
| Warden | M/Yoruba | 39 | Tertiary | Teaching | 220,000NGN |
| Wilmot | M/Yoruba | 47 | Secondary | Civil service | 240,000NGN |
| FGD3b: Youth Female Group (18-30 years) | | | | | |
| <i>Serials</i> | <i>Sex/Ethnicity</i> | <i>Age</i> | <i>Level of education</i> | <i>Occupation</i> | <i>Level of income</i> |
| Fiona | F/Yoruba | 24 | Nil education | Catering | 60,000NGN/yr |
| Frances | F/Yoruba | 28 | Nil education | Housewife | Nil |
| Felicia | F/Yoruba | 20 | Home tutoring | Trading | 60,000NGN |
| Majorie | F/Yoruba | 28 | Primary | Tailoring | 80,000NGN |
| FGD4b: Youth Male Group (18-30 years) | | | | | |
| <i>Serials</i> | <i>Sex/Ethnicity</i> | <i>Age</i> | <i>Level of education</i> | <i>Occupation</i> | <i>Level of income</i> |
| George | M/Yoruba | 29 | Nil education | Artisan | 60,000NGN/yr |
| Philip | M/Yoruba | 30 | Primary | Artisan | 50,000NGN |
| Pontius | M/Yoruba | 28 | Nil education | Trading | 60,000NGN |
| Poker | M/Yoruba | 22 | Primary | Mechanic | 80,000NGN |
| FGD3c: Youth Female Group (18-30 years) | | | | | |
| <i>Serials</i> | <i>Sex/Ethnicity</i> | <i>Age</i> | <i>Level of education</i> | <i>Occupation</i> | <i>Level of income</i> |
| Veronica | F/Yoruba | 19 | Secondary | Sales Girl | 30,000NGN/yr |
| Vivian | F/Yoruba | 26 | Primary | Tailoring | 60,000NGN |
| Sapphire | F/Igbo | 21 | Nil education | Housewife | Nil |
| Sarah | F/Hausa | 27 | Nil education | Trading | 36,000NGN |
| FGD4c: Youth Male Group (18-30 years) | | | | | |
| <i>Serials</i> | <i>Sex/Ethnicity</i> | <i>Age</i> | <i>Level of education</i> | <i>Occupation</i> | <i>Level of income</i> |
| Solomon | M/Yoruba | 24 | Primary | Trading | 60,000NGN/yr |
| Stanley | M/Yoruba | 25 | Arabic education | Artisan | 16,000NGN |
| Solar | M/Yoruba | 21 | Nil education | Artisan | 20,000NGN |
| Bailey | M/Igbo | 18 | Nil education | Artisan | 12,000NGN |

FGD 5 - RPMG: Mixed Group (24 -57 years)

| Serials | Sex/Ethnicity | Age | Level of education | Occupation | Level of income/year |
|----------------|----------------------|------------|---------------------------|-------------------------|-----------------------------|
| Ruth | F/Yoruba | 24 | Secondary | Applicant | Nil |
| Rita | F/Yoruba | 29 | Tertiary | Civil service | 280,000 |
| Molar | M/Yoruba | 47 | Secondary | Business | 420,000 |
| Janice | F/Igbo | 36 | Tertiary | Civil service | 300,000 |
| Major | M/Yoruba | 57 | Tertiary | Medical Records Officer | 360,000 |
| Andrew | M/Igbo | 28 | Secondary | Trading | 140,000 |

The summary of all my study participants is presented in Table 6.

Table 6 Summary of all study participants

| S/N | Participants' category | Sex distribution | | Total |
|-----|---------------------------|------------------|------|-------|
| | | Female | Male | |
| 1. | FGD | 24 | 26 | 50 |
| 2. | Community rulers | 0 | 2 | 2 |
| 3. | Community/opinion leaders | 1 | 1 | 2 |
| 4. | Community health workers | 2 | 0 | 2 |
| 5. | Biomedical researchers | 14 | 16 | 30 |
| | Total | 41 | 45 | 86 |

To ensure lucidness of my discussion, it is vital to establish the *endoxa* (as discussed in Chapter six on ‘Empirical research in bioethics’) by discussing the community leadership structure as described by my study participants.

8.2.3 Community leadership structure

My participants described the community leadership structure, the actors and their roles, and the interactions between the various actors during their discussions or responses (Refer figure 7). The community leadership structure is made of two levels of leadership, namely traditional and political. The civil or political administrative structure is made up of a local government council headed by an elected Chairman who coordinates government-sponsored programs like education, health, road construction, and so on, at grassroots level. The Chairman is assisted by supervisory councilors who oversee these programs, for example there is a supervisory councilor for health who supervises the community health centers through the community nurses and midwives, and other health workers. One of the community health workers in her response to the question, who are ‘the representatives to contact before conducting research in the community?’, stated:

***Felicitas:** ‘in that case, you will start from our local government. The HOD of our department (in the local government council office) will (should) be aware, then readily everybody will be informed.’*

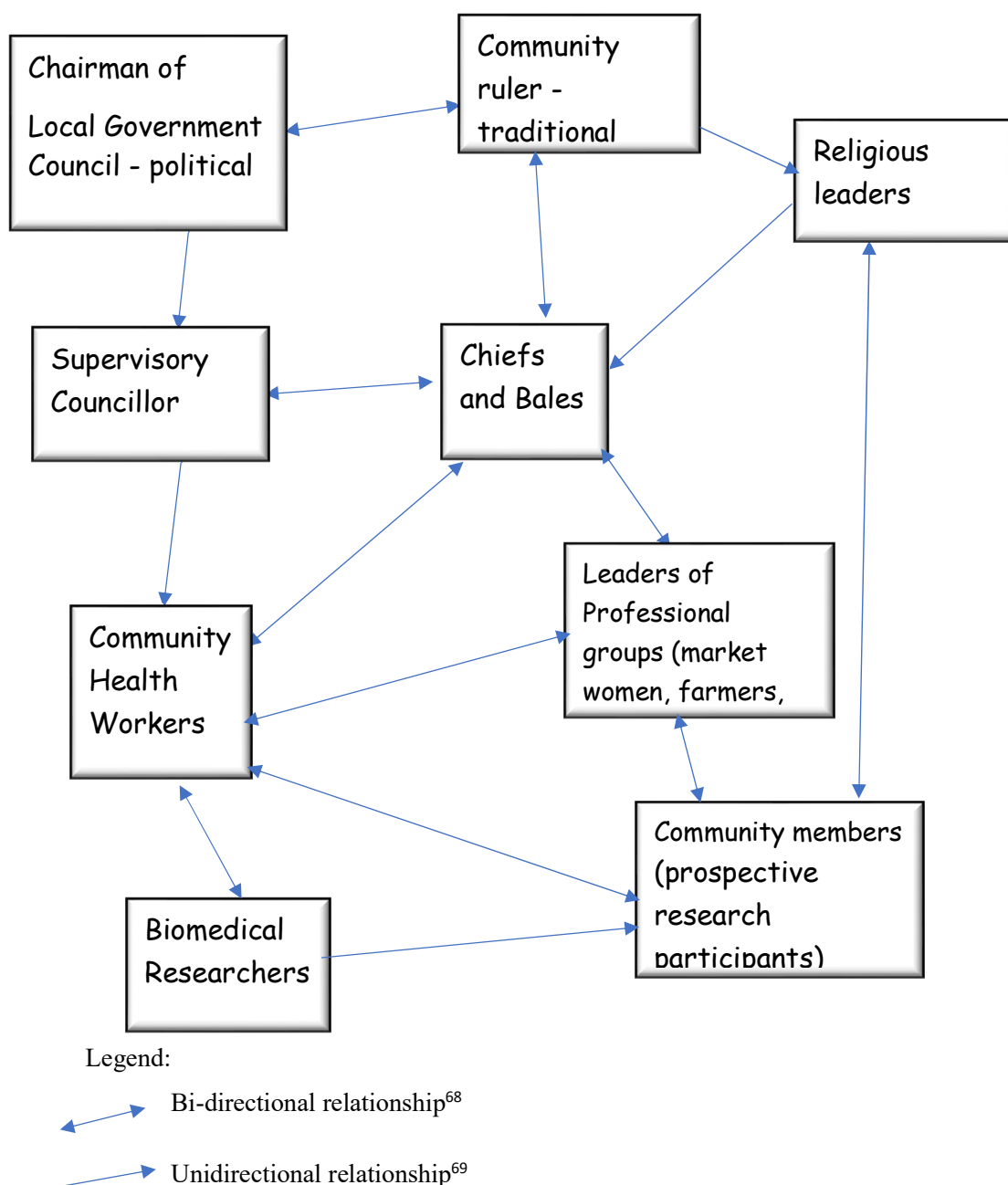
The other level is the traditional authority structure which consists of the community ruler referred to as the Oba, assisted by the chiefs. In some areas of the communities there are chiefs called ‘Baales’ who serve as the representatives of the Oba. These two tiers of authority structure interact and relate in a way to ensure the progress of the community. They exchange information

on matters that affect the community. This was described by one of the biomedical researchers like this:

'Within a community in my setting, we have political leaders and we have like the Baale and the Obas, we have the religious groups, both the Christians and the Muslims. The best way to get the people is through their leaders in an open transparent way, you know, you can't just jump on a person in the community and start talking research, especially if it is going to be a research that will be involving the community. It may just be a councilor because we have political leaders too, so as to be able to penetrate the community well. If you're able to convince the leaders, that's the community entrance, getting into the community, that's the first thing you have to do and its important in research.' **Dr Mendy**

Apart from these two levels of leadership, the respondents identified several community groups, which I have labelled 'subsidiary leadership structures', that can play significant roles in community engagement. They include religious leaders, professional groups like farmers, hunters, commercial motorcycle riders (locally referred to as 'okada'), and market women. The religious leaders and these professional or social groups can play important roles in community participation of research. This schematic diagram depicts the social relationship and interdependence between the community leadership and prospective research participants as described in my data.

Figure 7 – Schematic representation of the community social network structure



⁶⁸ Bi-directional relationship was determined from data. It reflected a two-way interaction between the two groups of participants as described by the responses from my study participants

⁶⁹ Uni-directional relationship is a one-way interaction between the two groups of participants. This was based on my data.

CHAPTER 9

Decision Making in Biobanking: Facilitators and Barriers to Participation

9.1 Introduction

This chapter addresses the first part of my main research objective; to explore the views, opinions and perceptions of potential research participants' willingness to participate in genomic research, vis-à-vis donating bio-specimens and agreeing to the storage and export of these specimens. The factors that could influence their decisions to participate were explored. Their responses were compared with the opinions of their community leaders and health workers, and biomedical researchers to determine degree of consensus and cohesion between the groups (data or informants' triangulation). I established the *endoxa*⁷⁰, which in this scenario is to determine the understanding of my study participants, the community members and biomedical researchers, of the concept of genomic research. Thereafter, I discussed the themes that emerged from the analysis of their responses.

9.2 Discussion of findings

The success of genomic research depends on active participation of prospective research participants and their willingness to donate bio-specimens. Getting the cooperation of the public demands appreciation of what factors influence their decision to donate, and consent to storage and export of their samples⁷¹. Before I discuss the themes on what influenced their decisions to

⁷⁰ This is based on the five components of the symbiotic empirical ethics approach to integrating theory with data as proposed by Frith (2012). I discussed this earlier in chapter 6, section 6.5.2.3, p. 127

⁷¹ The concept of biobanking which involves storage, and sometimes export, of bio-specimens is an integral component of genomic research. This type of research makes use of bio-specimens for genomic analysis and relate the results to individuals' clinical data to elucidate the relationship between phenotypical expressions, for example diseases or response to drugs, among different individuals and their genome sequences. I discussed the details in chapter two, section 2.3.2, p 14.

donate, it is useful to set out the circumstances by exploring the understanding of my respondents regarding genomic research.

9.2.1 Study participants' understanding of genomic research

To begin my discussion, I present the responses of the potential research participants and the biomedical researchers to questions on what genomic research is. My goal here is to determine their genomic health literacy, so based on their responses I generated the final themes which reflected how much information on genomics they possessed.

The understanding of my study participants was related to *genomic literacy*⁷². Their responses generated themes which reflected how much they understood about genomics and genomic research. The major themes revealed a continuum that represents an increasingly complex form of knowledge, from *unfamiliarity*, *genomic science literacy*, to *genomic health literacy*. Genomic science literacy is determined by responses that describe genomic research as research on genes and its scientific applications while genomic health literacy by responses that refer to the human genome, its utility and health-related benefits. The objective of representing the themes along this continuum is not to label a response but to illuminate and contextualise their views.

The majority of the potential research participants expressed *lack of familiarity* with what genomics and genomic research is though there is a general awareness of some diseases described as 'common in families' (familial) or 'inherited through the blood' (genetic transmission). However, a few of them (specifically four of the FG discussants which included one adult female with tertiary education, two adult males - one with tertiary, the other with

⁷² The definition of genomic health literacy was discussed in chapter three, section 3.2.1.4, p. 34

secondary - and one youth female with tertiary education) expressed genomic science literacy by linking genomic research to sickle cell genotyping. For example, one of the adult females said,

'it is like doing genotype testing. Some people do not want to know their genotype whether I am AS or SS, and the fear of that I will not get someone to marry' **Charlotte.**

The two adult males also related genomics to other tests that can help predict diseases like doing prostatic specific antigen (PSA) assay for prostatic cancer. The adult male that used the example of testing for prostate cancer to illustrate his understanding said,

'I can use the example of prostate cancer (for genomic research), if we know we can control it if we can predict, to run PSA for men at very earlier stages' **Taylor.**

The community health workers expressed genomic science literacy by relating genomics to sickle cell disease and the use of blood tests for making diagnosis of inherited diseases and for development and confirming efficacy of vaccines. One of them stated,

'it is like doing genotype for SS or testing vaccine, so researchers are doing such thing like our own vaccine now' **Felicitas.**

The community elders admitted to their unfamiliarity and asked for the meaning during the interview, as illustrated with this example,

'You are the one that will explain to us because we do not know, and you talk to the people just the way you have explained to me' **Elder Johnson.**

The community elders stated that it was the duty of the researchers to educate them and the community on what type of research they (the researchers) wanted to conduct. This implied that the responsibility of educating the potential research participants and the community was

perceived to rest on the shoulder of researchers who are expected to have good understanding of genomic research and possess the ability to communicate genomic information to the public.

The lack of genomic health literacy has been reported by several researchers, and it is an observation that cuts across communities in developing and developed countries, but worse in developing world. For example, Gao and colleagues (2014) reported little knowledge of bio-specimen banking among the Asian Americans and noted that they would benefit from educational campaign to address the knowledge gap (Gao et al., 2014). Similarly, Haga *et al*, based on review of studies from United States, Australia and Europe, emphasized that variable health literacy and genetic knowledge pose significant challenges to engaging the general public in personal genomics, specifically with respect to promoting risk comprehension and healthy behaviours (Haga et al., 2013).

There is however an increasing research interest to clarify individual's perceptions, beliefs and factors that influence understanding of genomics, although to date this has not been framed in terms of health literacy. According to Lea *et al*, investigation of the public's understanding of genomic terms and concepts is an essential component in the design of effective communication strategies for genomic research (Lea, Kaphingst, Bowen, Lipkus, & Hadley, 2011). Furthermore, Lanie and colleagues explored the public's understanding of genomics concepts using qualitative interviews with 62 American adults and revealed that participants had a limited understanding of what genes are, how they are inherited and where they are in the body (Lanie et al., 2004). My data corroborated these earlier studies.

On the part of the biomedical researchers, eight (none of whom have engaged in genetic research before) were unfamiliar with concepts of genes and lacked genomic literacy. They had heard about genes but did not talk about genes and genetic research except when prompted. Also,

they did not talk about human genome and its healthcare applications even when given cues.

Some acknowledged that they did not know anything about genomics.

Interviewer: *Can you please tell me what you understand by genomics?*

Dr Max: *Yes, genomics, genomics, genomics (muttering repeatedly)*

As ethics? (probing)

Interviewer: *No, not as ethics. I just want to know your understanding of genomics or research in genomics.*

Dr Max: *It has to do with people's perceptions and views about different things.*

Interviewer: *No, like when scientists do research in genomics... have you heard of it before?*

Dr Max: *I have not heard about it before. So, you can enlighten me*

One researcher pointed out that genomic research is novel to the country therefore researchers are not familiar with it.

'However, it seems genomics research is relatively new to us in this country. It seems a bit new to us. Many people are not aware of and have not done any work (research) on genomics here in Nigeria, for instance I am not aware of it' **Dr Shade**

Approximately half (fourteen) of the biomedical researchers showed genomic science literacy by talking about genomics research in the context of genes and genetic research. These researchers did not relate genomics or genomic research to the human genome and its applications to healthcare. Examples of their responses are stated below;

'I think genomic research has to do with the genes' **Dr Sandy**

'Genomics research (kind of) entails genetic research, molecular research into the aetiology of some disease conditions' **Dr Sharp**

Another researcher with genomic science literacy said genomic research has to do with DNA and genetics, but eventually admitted that he did not have much knowledge of what genomics is.

'I know that you're looking at the DNA, you're looking at genes, it has to do with genetics, so you're mapping out genes to know if you have this gene. I don't know much but I think that's what it entails' **Dr Mendy**

Eight, including the three genetic researchers, displayed *genomic health literacy*. They talked about the human genome and its applications to health care especially in relation to sickle cell anaemia. This is not unexpected because sickle cell disease (SCD) is a genetic disease prevalent in Africa, especially West African sub-continent (Grosse et al., 2011). Two of these researchers used examples of disease markers like APOe and BRCA, the genetic markers for apolipoprotein E and breast cancer respectively, to illustrate health-related applications and benefits of genomics.

'Genomic research test for genes which are components of the genome, it's like someone being born with sickle cell anaemia, there is nothing you can do about it. You can only say I know this child has sickle cell or this person has APOe gene' **Dr Monty.**

'Well, I know that when you talk of genomics, it has to do with the genome. I think that is a way of identifying diseases, then we will be able to find solutions to diseases such as diabetes, hypertension, and so on. The potential benefit is huge. But at the same time, we talk about designer babies, where couples will be able to define the kind of baby they want, there is this opportunity for parents to specify the kind of traits they want from their children' **Dr Moon**

There was no difference in the responses of the three researchers who were involved in genetic research and the seven who were genomic-health literate. Overall, the researchers were more genomic-science literate than genomic-health literate. Those who were genomic-health literate had understanding of human genome and related genomic research to familial genetic disorders in their environment like sickle cell disease. This finding corroborates the observation of an earlier study that reported that knowledge of genomic tests was limited to paternity and sickle cell genotype among Nigerian Africans (Fagbemi & Adebamowo, 2014).

My themes have parallels with the theory-based framework proposed by Smerecnik *et al* in terms of ascending level of knowledge. Smerecnik's framework distinguishes between three different types of knowledge of genetic risk factors namely, awareness knowledge, how-to (practical) knowledge, and principles (theoretical) knowledge. This framework graded knowledge of genetic risk factors from levels of awareness to a better understanding of how they impact health (Smerecnik, Mesters, de Vries, & de Vries, 2008). This continuum of levels of understanding is also illustrated by my themes and allows for assessment of how deeply an individual understands the concepts of genomic research.

Most of the studies on understanding of genomic medicine were conducted among health-care providers, not strictly among scientists-researchers. Notwithstanding, clinicians do engage in genomic research and are thus expected to possess appropriate knowledge and skills in genomic medicine for educating their potential research participants before seeking their consent. Studies by Jeffrey *et al*, Marzuillo *et al* and Laskin *et al* clearly documented knowledge gaps in genomic health literacy and emphasised that this constitutes a potential limitation in ensuring high ethical standards of informed consent due to misinformation and poor comprehension (Botkin *et al.*, 2015; Marzuillo *et al.*, 2014; Laskin *et al.*, 2016). Similarly, knowledge gap was demonstrated by

Merdad *et al* when they assessed knowledge about biobanking among healthcare students and observed that 44% and 27% of the students were aware of the Human Genome Project and biobank respectively. They concluded that there was a notable lack of knowledge about biobanking and human genome project among the students and recommended that healthcare curricula should be enhanced by including educational programs on genomic medicine (Merdad et al., 2017) .

Low levels of genomic health literacy found among the potential research participants and biomedical researchers may serve as a barrier for developing culturally and linguistically appropriate communication strategies to pass information to the community during the consenting process, prevent community-based participatory research and the successful implementation of genomic research in the community. To remove this barrier, genomic health literacy is a critical issue for researchers to consider as they prepare to engage with genomics medicine. They need to develop ways to communicate genomic research information to the public and individual research participants. Communicating genomics information in ways that maximize understanding and promote public interest and participation is very important given the rapidly expanding capabilities of genomic technologies (Lautenbach, Christensen, Sparks, & Green, 2013).

At a National Human Genome Research Institute Meeting⁷³ in 2011, it was observed that limited genomic literacy may adversely impact the public's understanding and use of power of

⁷³ The National Human Genome Research Institute (NHGRI) at the National Institutes of Health in the US organized a workshop in Rockville, Maryland, between November 17 and 18 of 2011, to examine the challenges of achieving genomic literacy for the public, from K-12 to adult education, and the role of the media in disseminating scientific messages that would enhance genomic literacy. The workshop participants, who were drawn from various backgrounds including biomedical researchers and bioethicists, agreed that genomic literacy will only be achieved through active engagement between genomics experts and the different constituencies of the public.

genomics in health care and public health, and that perspectives of lay communities on genomic health literacy have been explored in lesser degree. Therefore, the meeting recommended community conversations, a community engagement approach that explores community opinions and attitudes about their genomic literacy needs (Hurle et al., 2013). The objective is to present information on genomic research in a way that people can understand at their linguistic level to impact behaviour positively in intended ways and ultimately improve health or environmental outcomes. It is expected that researchers should have a higher level of understanding and skills than their intended or potential research participants. These observations underscore the urgent need for biomedical researchers who are interested in genomic research to improve their knowledge, not only of pure genomics, but also of its ethical issues.

9.2.2 Willingness to donate bio-specimens for genomic research

The qualitative analysis of the responses of the potential research participants identified factors they would consider before deciding to donate their biological samples for genomic research, and this yielded the following themes which I discuss below:

- a. Blood and spirituality
- b. Trust is everything
- c. Respect for communal values
- d. Individual understanding of research
- e. Benefits of the research
- f. Cultural and religious beliefs

9.2.2.1 Blood and spirituality

The potential research participants expressed willingness to donate their blood specimens for genomic analysis, provided they knew what their samples would be used for. This is because

they were afraid that their blood samples might be used for ritual purposes, and more importantly was the spiritual symbolism of blood and its effects on donor's life if used for ritual purposes, in their words, *'life is in the blood'*. This phrase was repeated by majority of the focus group discussants, for example, two adult females said,

'Life is in the blood, he cannot just take our blood' **Delilah**,

and

'What kills is usually in the blood. Once there is a problem with one's blood, then death is imminent' **Mary**,

and an adult male expressed his view like this,

'Nigerians, Africans we have these beliefs, so we may not want to give out our blood.

Blood is very precious to us, it has to do with our culture and belief' **Warren**.

Also, some of the biomedical researchers expressed similar views about blood when they gave their opinions on the perceived readiness of the research participants to donate their blood samples as exemplified by the response of this male researcher,

'Because we are very culturally and spiritually inclined and so many things tied to spirituality, culture, especially collection of blood, people attribute blood to life so, it's not something that its quite minimal, that's why it's a major decision making for that person at that point in time' **Dr Mendy**.

This symbolic representation of blood among the potential research participants is a barrier to genomic research participation and growth of biobanks.

According to Grietens *et al* in their paper, '*Doctors and Vampires in Sub-Saharan Africa: Ethical Challenges in Clinical Trial Research*', this symbolism attached to blood was born from historical antecedents based on local rumors surrounding 'blood stealing' or 'blood selling', and it is a reflection of implicit contemporary structural inequalities and the social distance between communities and public health institutions (Grietens *et al.*, 2014).

For decades, it was believed that blood is no ordinary substance. This belief is one of the oldest among those pertaining to the body and bodily fluids. In most developing countries, science and reason have not erased the many myths associated with blood, and these symbolic representations of blood are still commonly encountered by genomic researchers involved with human bio-specimens. A good example is the experience of researchers with native Hawaiians when the tribe reacted to the use of body parts for genomic research because it threatened to alter their worldview and traditional ideology of body parts like blood, hair, nails, and teeth having a spiritual essence, so they considered research on these specimens to be ethically and culturally wrong (Santos, 2008).

When the question why people disagreed to donating their blood was posed to one of the community leaders, he said that it is a traditional belief that dated to the olden days.

Elder Johnson: *'The problem started in the olden days because this is my line of work, we can use such blood to harm them, we can also use it to help them. You (researcher) want to use it to help them now like you said but they (people) will not think about the good that will come out of it but about the bad of the olden days. That's what happens'.*

To further analyze the association between blood and its symbolic interpretation within the context of African religious beliefs, I interpreted the meaning of this theme 'blood and

spirituality’ from the viewpoints of my study respondents based on their beliefs and cultural settings. From their responses, they attached significance to blood and other biological specimens, because any body part or fluid has tendency to be used for ritual practice in the Nigerian and sub-Saharan African settings. Blood can be viewed as symbolic, just like the English saying goes, ‘blood is thicker than water’ implying that blood is never ‘just blood’, rather it has powerful associations embedded in a variety of well-developed cosmological schema, from Christian ritual manipulations of the ‘blood of Christ’ to the common theory that women’s menstrual blood coagulates to form a growing fetus (Wharton, 1992).

In the context of my data, they viewed donation of blood as being synonymous with donation of life, relinquishing a precious possession that makes you vulnerable to ‘evil manipulations’ because whatever is done to your blood will definitely has effect on you. Blood is perceived at the paradox of life and death, that is the power of the symbol of blood is neither good nor bad, it becomes beneficial or harmful depending on its application (Charbonneau & Tran, 2012). Some writers have stated that blood is not a symbol of life, but rather, as a substance, it truly is life. Its regenerative, life-saving and medical virtues have been recognized. It may also be related to the religious beliefs of the people, as blood is believed to circulate within the body. The transition of blood outside the body creates disorder, ambiguity, and it becomes a blemish and a stain (Garraud & Lefrere, 2014). This conception of the integrity of the body is found in both Christian and Islamic traditions. For the Christian faith, the biblical phrase in Leviticus chapter 17 verse 11, *‘for the life of any flesh is in the blood’* buttresses this (Wycliffe Bible Translators, 1996: p.101).

Despite the reservation expressed by the potential research participants on the issue of blood or body parts donation, they were still willing to donate provided the researcher has gained their trust, and they were certain of what their samples would be used for.

9.2.2.2 Trust is everything⁷⁴

Trust was a cardinal and recurring feature of the responses of the potential research participants, community health workers, and the community leaders. Similarly, the biomedical researchers reinstated trust as an important facilitator for getting the cooperation of the potential research participants in biobanking. The research participants discussed putting their trust, not just in the researcher, but also in the research institution and the community leadership. Trust echoed in their readiness to comply with the community leaders' decision taken on behalf of the community. They also stressed that since the researcher 'is a stranger' to the community, they needed to know and confirm the researcher's identity, as well as the integrity of the research institution before deciding to participate. They talked about having trust in their leaders to scrutinize the researchers and confirm their identities thereby ensuring their safety. So, the choice to participate is determined by the level of trust in the researcher, the affiliated institution and community leaders.

*'For medical research, if I trust the researcher and organisation with my blood sample, I do not mind where they take it to so far they have my good intention at heart' **Poker.***

*'You have to inform the community ruler and the chiefs, we have trusted leaders. Once you informed them you have, by so doing, informed the people' **Philemon***

⁷⁴ Trust is a recurring theme in the responses of my study participants, but the concept varies depending on the topic under discussion. The concept of trust as regards willingness has to do with confidence in the researcher and the research institution to use bio-specimens in an ethical manner.

In addition, they said they would have to trust the researcher not to use the samples collected for money-making rituals or voodoo practices to harm individuals, which according to some were common in the society. Here are some excerpts from the respondents' opinions:

'you are warned that anything pertaining to your blood just be very careful because at times at the hospital they even take people's blood, placenta do rituals, for you to release your blood, it will be very hard' **Anne.**

'And again, if I am sure that my blood sample is going to be taken just for the medical reasons that I have been told, that is fine but so many things happen around us, now people use it for rituals' **Flora.**

Glaeser et al (2000) and Baron et al (2004), both defined trust as 'the commitment of resources to an activity where the outcome depends upon the cooperative behaviour of others' (Baron, Tonkiss, Savage, Tampubolon, & Warde, 2004; Glaeser, Laibson, Scheinkman, & Soutter, 2000; p.113). Therefore, trust is crucial to obtaining the cooperation of the community members for genomic research implementation. Several authors have indeed emphasized that maintenance of public trust in genomic research is essential (Chalmers, 2011; J. Murphy et al., 2009). Lack of trust will lead to lack of support and participation which may translate into biobank activities being stopped or abandoned.

Also, a sustainable ethical framework for bio-banking must rely on governance supported by institutional structures that are worthy of trust. Using a qualitative method of inquiry, Yarborough *et al* demonstrated that good relationship between research institutions and communities build greater public trust in biomedical research (Yarborough et al., 2013). In another study using a survey method, the authors used multivariate models to assess patients'

attitude to and understanding of genomic research and revealed that trust in the biobanking institution was one of the predictors of willingness to participate in biobanking (Rahm, Wrenn, Carroll, & Feigelson, 2013). Similarly, a mixed-method study by Gaskel *et al* that examined public perception of biobanks in Europe revealed that trust is a pre-requisite for willingness to participate in biobanking (Gaskell et al., 2013).

George *et al* in a systematic review of 44 publications identified mistrust, as not just an important shared barrier among four racial/ethnic groups in the United States, but expressed as the researcher's agenda not serving the community, the fear of purposeful mistreatment and experimentation often characterized as being treated like a 'lab rat' or 'guinea pig', and signing informed consent related to the perception that individuals are relinquishing their rights and providing the researcher with legal protection against any harm that may be inflicted onto the participants (George, Duran, & Norris, 2014). Therefore, trust is the cornerstone of successful implementation of genomic research, and the foundation for sustainable governance of biobanks.

9.2.2.3 Respect for community values

The majority of the male and female adult respondents based their willingness to participate in genomic research on the consideration of communal values like respect for decision of the community leaders and family members, especially family heads. They associated their considerations of community leadership approval and opinions of family members to compliance with traditional practices and norms, which may be expressed simply as 'doing it the way we have always done it in the community'. Some of the adults felt that research that involved the community, unlike doing a test for an individual in the hospital, required approval of the community leaders for participation. This underscores the importance of community engagement in genomic research, and the appreciation of the existing authority structure in research settings

for community collaboration. The adult females agreed that decision to participate must be approved by their spouses who are the heads of the families as exemplified by the response of one of the adult females,

‘Father is the head of the home. The mother cannot just take decision without the father’

Mary.

The adult males talked about discussing their decisions with their wives before deciding to participate. Also, the adult males expected their wives to discuss with them and get their consent before participating thereby portraying a form of ‘shared paternalism’ or ‘shared decision making’. The shared paternalism, which has also been referred to as ‘soft paternalism’ (Norheim, 2006), is akin to the shared decision making concept that has gained acceptance in physician-patient relationship. The shared decision making concept is defined as ‘an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported, while considering their options, to achieve informed preferences’ (Vučemić, Mahmic-Kaknjo, & Pavlicevic, 2016; p.62). The male and female adults therefore described a ‘shared decision’ making scenario rather than absolute patriarchy suggesting a transition from the expected patriarchy common in African society, though there is still some element of male dominance since the decisions of the female adults must be approved by their spouses. This observation corroborated an earlier study by Marshall and colleagues (2014) who reported how women clearly articulated their ability to express individual autonomy but showed respect to their husbands by discussing the research study with them, thereby calling attention to respect for traditional values (Marshall et al., 2014).

The biomedical researchers however believed that paternalism and patriarchy still exist among families within the community because women still depend on their spouses to make

decisions on health issues like research participation, acceptance or refusal of treatment, and consenting for routine or specific tests in the hospital. One of the researchers said,

'The women look up to their husbands. Many women do this because this is Africa. Many look up to the husbands for decisions regarding health issues. They get confirmation from the husbands, the woman is made to feel that she is subject to the husband, she must be controlled by the man. The man being the controller, is based on our cultural beliefs'

Dr Mouldy.

Although, according to some of the researchers interviewed, there are indications that female economic empowerment is gradually changing this scenario. More women are now educated and gainfully employed, and some are family 'bread-winners' hence assuming authority to take health-related decisions for family members. Two of the biomedical researchers expressed their views as stated:

'Decision making also depends on some factors, we know in our environment, it's the man most of the time. But then it also comes down to who brings the money into the family because, yes, the man supposed to be the head of the family, but if he is not gainfully employed, that responsibility may shift to the woman' **Dr Sugar.**

'Well in this community, decision making is majorly the man's responsibility, he is viewed as the head to a large extent even if both are educated and they are knowledgeable, the wife still asks the opinion of the of the husband. However, things are changing in recent times, these are days of women empowerment, some women can take decision' **Dr Soul.**

Patriarchy is defined as social organisation marked by the supremacy of the father in the clan or family, or the legal dependence of wives and children, and the reckoning of descent and

inheritance in the male line, and characterized by control by men with a disproportionately large share of power (Merriam-Webster's Collegiate Dictionary, 1999). Patriarchy occupies such a central place in African culture. According to Agulanna (2008), the low status accorded women in the social arena in African societies is due to partly religious and partly the patriarchal basis of African culture (Agulanna, 2008). The adult males, who are often regarded as family heads, are believed to take health-related decisions for their wives and children (Agulanna, 2008; Kritz et al., 1995; Tessaro et al., 1997). From existing literature, in countries without strong legal traditions of respecting individual freedom of choice, like most developing countries including the traditional African settings, married women could not take unilateral decisions on issues of research participation in genomic research, rather they comply with the decision of their husbands (World Health Organisation, 2002). However, a more recent study has shown that although men are typically described as house-hold decision makers in many African communities, decision-making are often more nuanced with many women using their agency to control the decisions made, and using strategies to exercise their choice in ways that safeguard important relationships within households in the longer term (Malmusi, Vives, Benach, & Borrell, 2014).

Patriarchy thus encourages gender inequality as it exemplifies power imbalance between partners. Gender inequality arises from systematic domination of women by men, usurping women's power to make crucial decisions about their health, employment, life-style and other issues of life. This affects decision-making when it comes to research participation. There have been commendable efforts by several global organisations including the United Nations and the World Health Organisations to address gender inequality and its consequences. These efforts,

which included addition of women's empowerment to the Millennium Development Goals⁷⁵ in 2000 and more recently the Sustainable Development Goals, resulted in more economic and financial power for women with less domination by the men (Malmusi et al., 2014).

The views of the biomedical researchers are supported by the trend observed in the literature which attributed gender inequalities to economic factors like individual income (an indicator of availability of economic capital, access to the labour market, and potentially the degree of independence and power within the household) as contributing largely to women's health (Malmusi et al., 2014) and authority to make health-related decisions. I discuss gender inequality and the patriarchal family system in African communities, including Nigerian, to buttress their influence on genomic research participation.

Gender equality and research participation: Gender-based power imbalances can negatively affect women's health. According to the theory of gender and power (TGP), there are three social structures that interact at the societal and institutional levels to influence health: economic inequalities (division of labor), male partner control (division of power) and, social norms and affective attachments around gender. For example, women with lower access to economic resources may have limited 'power' to attend school, enter or leave relationship, and inherit land. Male dominance and control can result in restricted mobility, less participation and authority in decision making for women. These deficits in power can affect women's functional autonomy (Conroy et al., 2016; Dash et al., 2014). It is this power imbalance that resulted in the

⁷⁵ Millennium Development Goals were eight goals which had remained the overarching development framework for the world for the past 15 years. The eight goals are to a) eradicate extreme poverty and hunger, b) achieve universal primary education, c) promote gender equality and empower women, d) reduce child mortality, e) improve maternal health, f) combat HIV/AIDS, malaria and other diseases, g) ensure environmental sustainability and h) develop a global partnership for development.

emergence of the feminist theory in ethics⁷⁶. Feminist ethical theories consider the impact of gender roles and gendered understandings on moral lives of individual human beings and draws attention to the power and power differentials inherent in moral relationships at individual, societal and organisational levels. This is the application of feminist theory to understanding the ethical realm (Hospice Friendly Hospitals, 2013; Lutzen, 1997).

Gender inequality is encouraged by the traditional health-belief system of sub-Saharan African cultures. For example, a qualitative study of socio-cultural context of health behaviour among some Nigerian communities revealed that most responsibility and blame regarding the care of children in the family were placed on women even though health-related decisions were taken by the men, and the system also placed social control over the adult female population. The author of this study, using anthropological field work and focus groups, also discovered that the health-belief system was changing due to impact of religion as Christian missions established hospitals where health education and enlightenment talks empowered and encouraged the women to make health-related decisions (Omorodion, 1993). Power imbalances were directly linked to limitation of women's functional ability to acquire health information, make decisions regarding and act to improve health. The power imbalance may constitute a barrier to female participants' willingness to participate in genomic research.

9.2.2.4 Individual understanding of research

Most of the prospective research participants, including the adults and youths irrespective of gender, stressed the need to know about the research before agreeing to participate. They opined that they would be motivated to participate if they knew what was expected of them, what samples would be donated, what their samples would be used for, and were certain of getting

⁷⁶ I discussed Feminist ethics in chapter two, section 4.3.3, p. 79.

results of the genomic tests. They agreed that detailed information on why genomic research was conducted should be disclosed to them. This underscores full disclosure of research, and effectively communicating with the people to give them opportunity to make informed choices. The respondents did not relate their understanding of research details to level of their education. They supposed that researchers should simplify the research information and present it to them in the 'language they can understand'.

There was consensus of views and opinions among the community elders and community health workers regarding the influence of understanding of research on willingness to participate. The community elders and health workers emphasized effective communication of research details in a linguistically appropriate and acceptable manner.

These are some quotes from the views expressed by the potential research participants during the focus group to illustrate this theme:

'If I have the preliminary information on what the test is all about, what you are going to discover I think that will give me chance to decide to be part of this' **Charlotte**

'To decide to participate in the research, all these bothers on information, getting people to know why this is done. Information why this test is done, using the language the people understand' **Philemon**

Similarly, the biomedical researchers agreed with the community members that giving detailed information on genomic research in a language that the people understand would facilitate willingness to participate in and positive attitude towards genomic research. The biomedical researchers pointed out that educating the potential research participants would help to demystify the superstitious beliefs attached to the use of bio-specimens, and suggested getting

someone who could be taught and would understand what genomics is, and effectively communicate with the potential research participants. The researchers suggested getting such volunteer from the community because someone who is familiar with the cultural beliefs of the community members would be more suitable.

‘In this environment, there are lots of superstitious beliefs. So, we really need to speak to another person who can come down to their level for you to get them to cooperate with you’ Dr Stone.

Unlike the potential research participants, the researchers emphasized the role of education in facilitating genomic research participation among the potential research participants. They believed that it is easier to get those who are better educated to participate than those who have no formal education because lack of education facilitates staunch adherence to traditional practices and cultural norms which may result in negative attitude towards genomic research participation.

‘Lack of education is one. People are not well educated, they are not well enlightened. They feel that they should continue in the way their fathers have been doing it. They may not see reason why they need to participate’ Dr Mouldy.

‘One really need to take that into consideration; level of education. The more educated they are, the (more) better you can get their cooperation. The level of education is very important’ Dr Mole

This observation, that is the impact of level of education on willingness to participate in genomic research, I posit, may be explained by a concept of social capital theory⁷⁷ – the strength

⁷⁷ Social capital theory is discussed in section 9.2.3, p. 230.

of position proposition. This concept emphasises that the better the position of origin of a member of a network, the more likely it is that the member accesses and better use the social capital. This tallies with the views of these biomedical researchers that the higher the level of education, the easier it is to obtain consent because they perceived that the educated are more likely to understand the genomic research concepts.

Three of the biomedical researchers however did not agree to demonstrate that this observation is not invariable, as an educated person may choose not to use available social capital within their network to influence their decision to participate in genomic research because of their strong beliefs in superstitions, and thus not be empowered. These three opined that level of education has no influence on the superstitious beliefs of the community members, but they agreed with the fact that individuals who knew about and understood genomics, not necessarily due to educational level, were more likely to participate. This underscores the importance of genomic health literacy. One of the three biomedical researchers gave an example to illustrate this:

‘Level of education does not even affect superstitious beliefs in our community, for example an educated colleague who observed that his older baby was envious of her younger sister (a new born baby) was asked to use the baby’s bathwater to bath the older sister. So, he used the same water to bath the two. This is due to influence of superstitious beliefs. People who already know of genomic research may readily accept to participate’
Dr Shade.

Several studies have reported that poor understanding of the reasons for collection or donation of biological specimens militate against community collaboration in genomic research (Grietens et al., 2014). Effective communication of research to potential participants is the key to

getting their cooperation. The UK biobank model for achieving public support for research using biological data, also emphasizes good communication as the key to effective collaboration and stressed that anyone undertaking research should do ‘research with people rather than on people (Thornton, 2009; Tutton, Kaye, & Hoeyer, 2004; UK Biobank Coordinating Centre, 2007).

Furthermore, in a systematic review of 44 articles that assessed the perceived barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders, the authors observed that a major shared barrier across all the racial/ethnic groups was lack of access to information on the research. The absence of bilingual research staff and informational materials were reported to be barriers among non-English speaking prospective participants (George et al., 2014), supporting the suggestion offered by the biomedical researchers as earlier stated. It was observed that having research staff who are representatives of the potential research participants was an important facilitator of research participation. The research staff could relate to and communicate with prospective participants in their own language and rhythm of expression, especially the African Americans, giving the research a ‘personal touch’ needed to encourage participation. The participants, especially the African Americans and the Latinos were more likely to participate when invited by a researcher or staff known to them (George et al., 2014). I believe the community health workers can serve this role because of their position in the community.

As regards the influence of educational level of community members on willingness to participate in genomic research, Porteri *et al* in a survey of 141 family members of patients in Italy, observed that the willingness to donate bio-samples for biobanking research was modulated by the education of the participants (Porteri, Pasqualetti, Togni, & Parker, 2014). McDonald *et al* also in a cross-sectional survey of 298 African Americans showed that education level had a

significant association with donation intentions as respondents with some college education and those who were college graduates were significantly more likely to be willing to donate a blood or saliva sample compared with those with less education (McDonald et al., 2012).

9.2.2.5 Benefits of research

All the community respondents (potential research participants) said they would consider the benefits from the genomic research before deciding whether to participate. The emphasis put on benefits far outweighed the concern for possible risks. Apart from direct benefits to themselves or future beneficiaries, some of them expressed desire for monetary compensation for participating. The direct personal benefits they identified included getting their genomic tests done at no cost and opportunity to get a medical check done, like a blood pressure check, by the research team. Below are some excerpts from their responses:

'I think it will give me the opportunity for medical checkup especially in this environment where people do not really do medical checkup, I think I should oblige' **Wilmot**

'Like I earlier said I will agree to testing either for research, and this time it is even beneficial and (also) in the future it will help me to prepare in case some disease is discovered' **Pontius**

There was consensus in the responses of the community leaders and health workers and that of the potential research participants on one hand, and between the responses of the research participants and the biomedical researchers on the other hand. Irrespective of gender and age, they all agreed that consideration of benefits that may accrue from genomic research would facilitate participation. Eight of the researchers felt that financial remunerations are important in motivating the prospective research participants to participate. These responses from the biomedical researchers support this theme:

'For example, if I am coming to carry out a genomic research that will involve taking blood samples, while am at it, there should be side attractions like taking blood pressure and so on. So it is like we are providing an immediate health service to the people to meet their immediate needs.' **Dr Stober**

'But when you have something to give them, something free, they will want to have it if it is going to benefit them. We cannot over-emphasize the place of financial gratification when people make such decisions. That is number one in my own opinion' **Dr Sharp**

The respondents also talked about the benefits to the larger community as emphasized by one of the adult males:

'Benefits to the whole community is emphasized, not so much to the individual. Emphasis is on the community.' **Barnaby**

Some of the respondents expressed the benefits to the community in the form of improvements in health delivery based on the outcome of the research to future beneficiaries and how the discovery of new drug or vaccine could prevent diseases affecting the members of the community.

'Once I have confirmation (that research is genuine) then there is no problem in allowing them (researchers) to do what they want to do, maybe it will be used for testing and development of drugs so that we can benefit from genuine drugs and cure our sickness' **Flora.**

Potential research benefits are often considered by research participants when deciding to participate in genomic research. It has been reported that individual and community benefits influence willingness to donate samples in biobank research (van Schalkwyk, de Vries, &

Moodley, 2012), and that participants showed positive attitudes towards genomic tests due to potential benefits despite the fact that they lacked personal experience of tests (Fagbemi & Adebamowo, 2014). Research participants are interested in benefits that accrue from research, usually putting these before the risks.

International ethics guidelines, for example the Helsinki Declaration, advise that research participants should be informed of the possible risks before the intended benefits (Widdows & Cordell, 2011) so that they will not be overwhelmed by the latter. In the systematic review by George *et al* (*ibid*), benefits to participants was identified as a shared facilitator of research participation. Mild monetary incentive, free lunch, or free health examination may positively influence participation in health research. In addition, receiving information about individual health and greater details about the study such as risks and safeguards were observed as benefits to participation thus serving as potential facilitators.

The monetary benefits suggested by the some of the biomedical researchers raised the concern of undue influence. The ethical appropriateness of using incentives in research involving human participants has continued to generate considerable confusion especially among research ethics committees. Undue influence is a distinct ethical issue different from coercion, it is considered as a corruption of judgement therefore, for most part when it is used to recruit and retain research participants, it is largely innocuous. Existing literatures suggest three main reasons that motivate people to participate in research: altruism (respondent is fulfilling a social obligation, a purpose important to the respondent), research-related reasons (interest of the respondent in the research or find the interviewer appealing), and egoistic reasons (I like it or because of the money), and some other reasons difficult to categorize (Singer & Couper, 2008). The issue of incentives relates to the egoistic reason for research participation.

However, Grant and Sugarman (2004) pointed out that it becomes problematic when there is a dependency relationship between the researcher and the participants such that the participants find it difficult to withdraw from the research, that is when compensation comes in form of ‘wages’ for a service rendered, and the participants become ‘contractors’ (Grant & Sugarman, 2004). Despite this drawback, monetary incentives are increasingly used to motivate research participants.

The role of incentives has been widely reported in the literature, and meta-analyses showed that money is more effective than non-cash incentives, and that prepayment is more effective than a promised incentive. In research, from the leverage-saliency theory, both monetary and non-monetary incentives are inducements offered to the participants to compensate for the absence of factors that otherwise might stimulate cooperation (Groves, Singer, & Corning, 2000), like offering cash for transport or time spent to participate, or providing lunch or snacks for focus group participants (Emanuel, Currie, Herman, & Project, 2005; Okello et al., 2013; Rodriguez, Torres, & Erwin, 2013; Tutton et al., 2004).

The leverage-saliency theory suggests that a single research design attribute will have different leverages on the cooperation decision for different persons (Groves, 2000). For example, in genomic research, an inducement in form of monetary incentive may stimulate a felt civic duty of altruism by the individual to respond positively to the research, while another person sees the incentive as an economic exchange for the burden of the interview or focus group participation.

From the cost-benefit framework perspective, economic forces operate in any research scenario so researchers must explicitly take them into consideration in motivating participation (Molyneux, Mulupi, Mbaabu, & Marsh, 2012). Individuals will participate in research if they

think the benefits, in whatever form, are greater than the costs. Though there is subjectivity in the perception of benefits and costs.

9.2.2.6 Cultural and religious beliefs

The cultural and religious beliefs of the research participants emerged as important considerations for genomic research participation. The potential research participants, irrespective of age and gender, agreed to consider the cultural practices before consenting to participate. The concept of symbolism of blood and fear of unethical use of their body fluids for ritualistic practices I discussed earlier have a cultural basis. Some of the male and female adult respondents used the Jehovah's Witnesses sect doctrine of not receiving blood transfusion, and Seventh Day Adventist doctrine of not eating or using any substance that contained pork as examples of religious beliefs that would affect their willingness to participate. Similarly, the community leaders and health workers stressed the importance of ensuring that any genomic research project that would be conducted in the community must not conflict with the community's cultural and religious practices, otherwise the people would not participate. The biomedical researchers expressed similar views especially the influence of religious beliefs on the willingness of the potential research participants to participate in genomic research. One of them put it this way,

'Even this genomics thing we are talking about, we know that some religions have a problem with working with the genes, hence some people will like to withdraw or remain neutral, they don't want to have anything to do with that; particularly Roman Catholics. Another common example is blood transfusion for the Jehovah Witnesses' Dr Max.

Another biomedical researcher emphasized the cultural and spiritual inclination of the potential research participants;

‘Because we are very culturally and spiritually inclined and so many things tied to spirituality, culture, especially blood collection, people attribute blood to life’ Dr Mendy.

One of the biomedical researchers said that some potential research participants might seek the opinion of their religious leaders before participating in genomic research;

‘For some people if their pastor said it is important for them to participate then they will quickly follow through because their pastor says it is good. So, religion is a very big influence on such decisions’ Dr Sharp.

A study that examined the factors associated with willingness to participate in bio-specimen research among 192 Chinese Americans showed that cultural factors like collectivism and Yin-Yang⁷⁸ beliefs leveraged their decisions to participate (Gao et al., 2014), thus a potential cause of lack of cooperation and high drop-outs in biobanking research. In another study among African Americans, cultural factors and religiosity were significantly associated with donation intentions. Respondents with lower levels of religious belief were more willing to donate when compared with those with higher level (McDonald et al., 2012). This observation is consistent with the view of one of the biomedical researchers,

‘But for those that will decline despite the potential benefits, of course it is very likely that, such people will have very low level of education and strong beliefs in their religion and culture’ Dr Misty.

⁷⁸ The concepts of Yin-Yang are central to Chinese religion and philosophy as a whole including both Taoism and Confucianism. The two principles, that is Yin and Yang, represent the interplay of opposites in life and in the world, life is viewed and lived inside the interplay of opposites: up and down, hot and cold, male and female, dry and wet, high and low, joy and sadness, peace and war, life and death, and so on. But good and evil pair is not included because in the grand scheme of things in Taoism, even ‘bad’ things are good, they are not evil. This belief influences every decision made by its adherents.

Another religious belief that militates against genomic research participation is the belief that scientists are ‘playing God’ with genomic research. In a focus group study, Harris et al observed that a theme that repeatedly arose was that human genetics is the domain of God, not humans, so the discussants were apprehensive of scientists causing changes to genes that may be deleterious to human existence (Harris et al., 2004). The recognition of the influence of the cultural and religious beliefs on willingness of the prospective research participants calls for continuing communication between the public and the scientific institutions and researchers.

9.2.3 Discordant views on decision making

There was divergence of opinions between the adult respondents and majority of the youths on the influence of community values and leadership on decisions to participate in genomic research. Most of the sampled youths felt they were not under compulsion to participate in genomic research based on the community leaders’ approval. Some of them claimed that with the level of their education they probably knew more about research than the leaders, were more aware of the benefits and possible risks, so they would make their choices based on their personal convictions. This discordance was further probed using a focus group of mixed respondents (3 adults and 3 youths) to achieve theoretical saturation of this theme. The session almost became confrontational as the youths insisted that, though they respected the position of the community ruler as being the ‘father of the community’, they were not bound to comply with the decision of the community leaders. The youths attributed their stance to a) being well-informed through the social media like the internet, b) their personal preferences, and c) desire for personal benefits. The adult participants stressed the need to comply with community decision, which is the decision of the ruler and the elders who serve as ‘gatekeepers’ and can therefore ensure

community protection from fraudulent researchers. Also, because it is the traditional norm, and for benefits of future beneficiaries through discovery of new drugs and treatments.

The views of the adults agreed with the opinions and expectations of the community elders, health workers and the biomedical researchers, who said that the potential research participants would participate in genomic research based on their respect for communal values and traditional norms. This discord reflects two ends of a spectrum. At one end of the spectrum is communitarianism, the position of the adults, and at the other end is a leaning towards autonomy or liberal individualism, the stance of the youths. The youths' stance cannot be described as 'pure' liberal individualism because they expressed considerations for others, therefore not entirely individualistic. The youths sought liberty to make their choices, and a commitment to equality in competence for decision-making, not ignoring community leadership and well-being of families and neighbours.

The adult participants' communitarian views emphasized the benefits to the community, the common good, suppression of individual choices, and importance of common bonds between people which are necessary for both their psychological well-being and their self-actualization. This is a philosophy that upholds the concept of the welfare of the society with foundational values of the collective good, common interests, solidarity, reciprocity and mutuality. This concept anchors the well-being of the individual and his or her identity within the social networks of the community. The communities build individuals just as much as individuals build communities (Etzioni, 2011; Gross, 2014; Stephen Macedo. 1, 1991). The individual therefore cannot engage in deliberative actions without prior consideration of communal interest. In communitarianism, the decision and action of a person should represent community interest since

community interests are the aggregate of individual interests. The responses from some of the adult and youth FGD participants are presented in table 7.

Generational shift: To explain the disparities in the responses of the youths and the adults, I argue that there has been a ‘generational shift’. A shift by the youths from the traditional communal-based decision-making process towards decision-making based on personal convictions. The youths talked about being better informed because of social media access to obtain information, thus empowered to make decisions on genomic research participation based on personal preference and conviction.

The review of literature on willingness to participate in genomic or biobanking research revealed that similar observation has been observed by some authors in western countries. For example in Florida, United States, Luque and Quinn (2013) in a qualitative study that investigated community members’ knowledge, attitude, beliefs and informational needs regarding biobanking showed that participants in the 30 years and above category were favourable towards participating if concerns of confidentiality and consent are addressed, but those in the 18-29 years age group were skeptical (Luque & Quinn, 2012). The skepticism of the youths in this study was not interpreted as a shift probably because there is no disparity in ethical principles explaining their responses and the older respondents. Also, a survey that assessed patients’ attitude to and understanding of genomic research in Colorado, USA, revealed that older age was a significant predictor of willingness to participate in biobanking research (Rahm et al., 2013). The authors did not explore the possible reasons for this observation. For my study, I argue that this shift is based on the impact of the social media on social networks within communities which can be explained by the social capital theory. I briefly discuss the social capital theory.

Social capital theory: Social capital is defined as ‘those resources inherent in social relations or networks which facilitate collective action’ (Andriani, 2013; OECD, 2007).

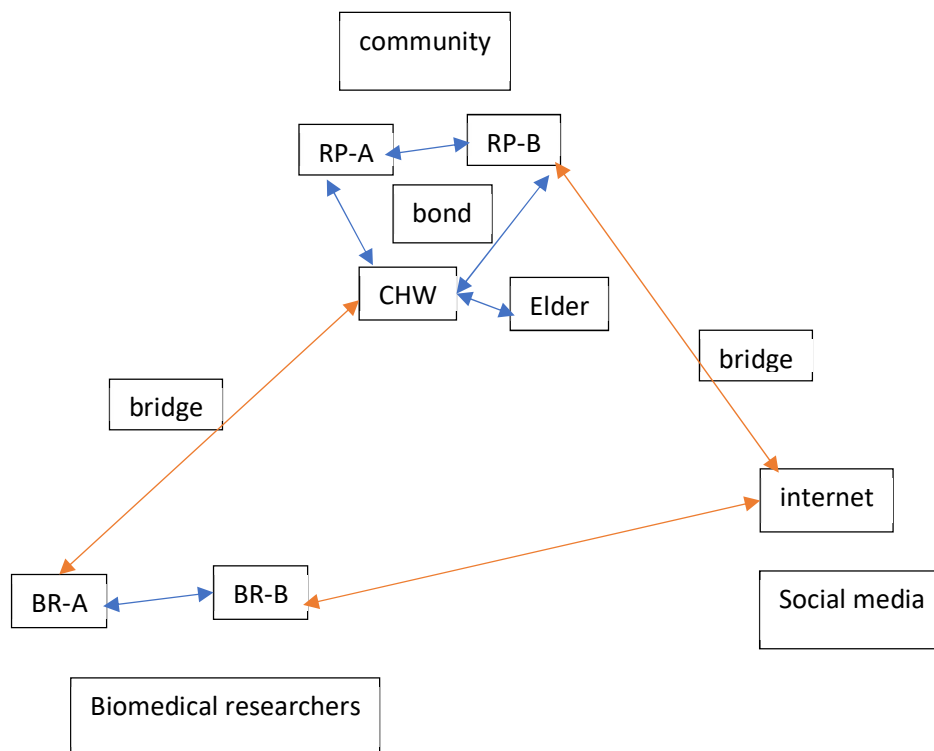
According to Lyda Hanifan (1916), social capital is those tangible assets that count for most in the daily lives of peoples; namely goodwill, fellowship, sympathy, and social interaction among the individuals and families who make up a social unit (Hanifan, 1916). It represents the links, shared values and understandings in society that enable individuals and groups within the community to trust each other and therefore work together. Communities are not made of unrelated individuals or groups, rather they include ‘social networks’ that comprise community groups or organisations like professional or social clubs, individuals, and the relations or ‘linkages’ among them. These social networks are crucial to every aspect of community engagement; from understanding the community, its cultural beliefs and practices, to mobilizing the community for health research including genomic research. It is this community leadership network that constitutes the existing structure employed by a researcher for community engagement process. It is crucial for a researcher to recognize this structure and comply with its uniqueness to prevent conflicts and misunderstandings that may arise from improper community approach and entry.

In social capital theory, three main dimensions of social networks have been described: a). *Bonding*: as exemplified by strong family ties and characterized by trust and reciprocity. Stronger bonding can however limit an individual to his circle without allowing for interaction for outside the circle. The advantage of bonding is that there is a strong reciprocity among members, consequence of a system with strong mutual obligations typical of African communitarianism; b). *Bridging*: this indicates the network of friends, neighbours, and acquaintances. The information and knowledge traded between groups allows the community to benefit from a diversified social

endowment accumulation and therefore more social capital, contributing to the wealth of the community. The lack of bridges may account for differences in development and growth between communities within the same region, and c). *Linking*: this indicates ties connecting individuals or groups to people and groups in positions of different political or financial power. This is a vertical relationship, thus allowing individuals or communities to access resources or information from institutions of power, like the relationship between community leaders and the community health workers (Andriani, 2013; Tzanakis, 2013). Granovetter's 'strength of the weak ties' within the social capital theory predicts that when bonding within members of a community becomes exclusive then the network becomes a closed one, reducing access to information which constitute extra resources possessed by other groups, resulting in lowering of social capital endowment but when intra-community bonds become weaker, stronger inter-community bridges emerge and result in empowering social capital (Baron et al., 2004).

Social capital theory predicts that higher associational activities inside a community are able to foster a sense of civic engagement where cooperation, reciprocity and mutual trust are developed and used to solve collective action (Andriani, 2013; Utz & Muscanell, 2015). Figure 8 illustrates the perceived social networks among my study participants. In the context of my data, the type of network or associations alluded to in the responses of the adult and youth study participants appeared to play significant roles in influencing their decisions to participate and what they considered as important factors that influence their decisions. The adult FGD participants based their decisions on considerations of community and family leadership, advice from family members, friends' suggestions and communal values which are reflective of the African communitarianism model, and mirrors the social networking seen in social capital theory, that is seeking information and guidance from community members they are bonded to and

linked with, to forestall untoward outcomes while functioning within the acceptable norms of the whole community. For the youths, the social interactions transcended the community, with social media becoming an important part of their networking, and a source of information to consult when making decision on genomic research participation.



Legend: RP-A – research participant A, RP-B – research participant B, CHW – community health worker, BR-A – biomedical researcher A, BR-B – biomedical researcher B

Figure 8 - Community bonding, bridging with research team and social media (illustrating Social Capital Theory)

Table 7 – Discordant opinions between the adult and youth FG participants

| <i>Responses from the adults</i> | <i>Responses from the youths</i> |
|---|--|
| <i>Barnaby: Benefits to the whole community is emphasized, not so much to the individual. Emphasis is on the community'</i> | <i>Linda: First is to consider how beneficial it is to me and then secondly the people around me.'</i> |
| <i>Charlotte: Once I have confirmation (that research is genuine) then there is no problem in allowing them (researchers) to do what they want to do, maybe it will be used for testing and development of genuine drugs',</i> | <i>Wood: Since I am more enlightened than the oba I will go ahead and agree, because I believe it will benefit me, and I will not just limit it to myself, but I will also try to educate the people around me</i> |
| <i>Williams: 'I am staying within the oba's community, there is nothing I can do because he has given the order, he is like a parent (father) to the community, whatever he says should be respected, no matter how educated I am'</i> | <i>Bailey: My own view, if I want to decide, first thing is I will consider how it affects me, does it affect me positively or negatively, then after considering how important it is to me. I will go to assess internet sources, so I read about it on the internet, asking people will not be the best for me. I decide on my own.</i> |

This 'generational shift' aligns with Granovetter's 'strength of the weak ties' within the social capital theory⁷⁹. Though the youths have a reciprocal social relationship with their families, strong enough to consider them when making decision, the linkage to social media appears stronger. The weaker bonds between the youths and their families and community leaders produced a stronger inter-community bridge between the youths and the social media allowing wider spread of information flow and a more diversified social endowment which influenced their decisions on genomic research and biobanking participation based on their personal convictions (Jiang & Carroll, 2009; Utz & Muscanell, 2015).

⁷⁹ This is discussed under Social capital theory in section 9.2.3, p. 231.

The social networks identified from the FGDs that influenced decision-making among adults are depicted in figure 9.

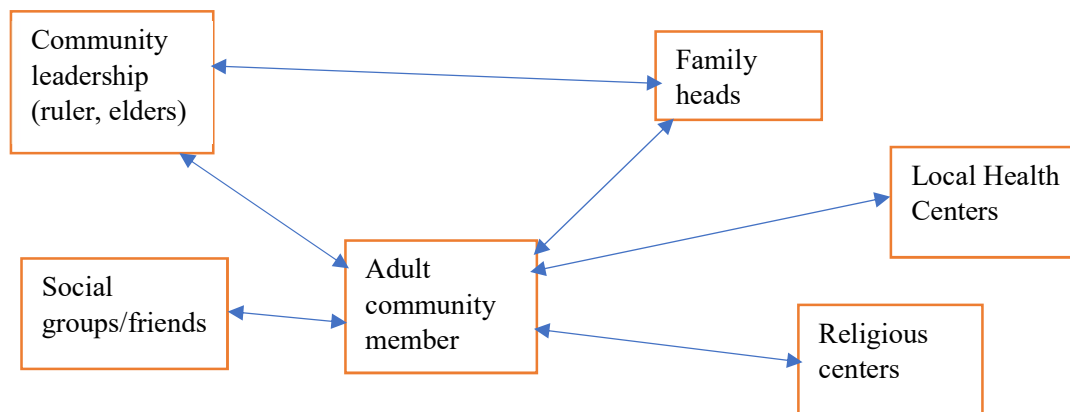


Figure 9 Social networking for FG adult discussants

Whereas among the youths, the social networks are as depicted in figure 10.

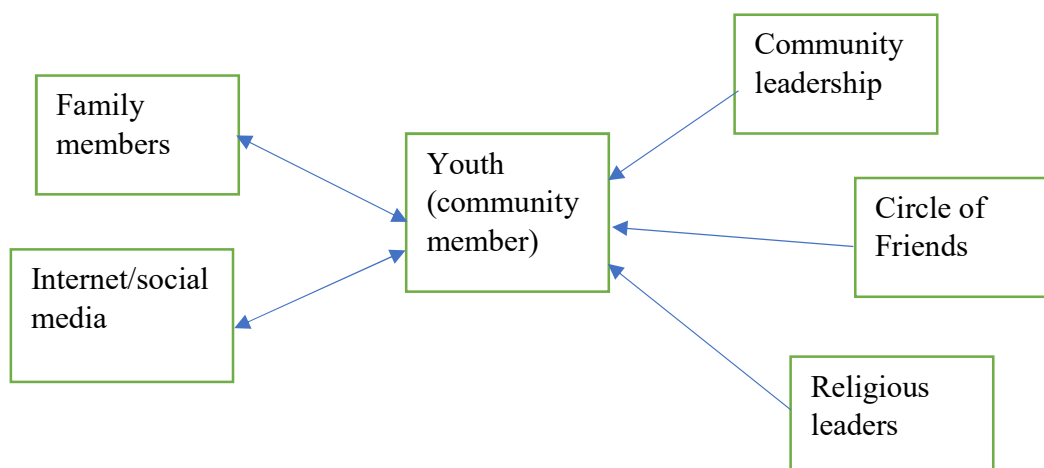


Figure 10 Social networking for the FG youth discussants

(In the diagrams, the bi-directional arrows indicate closer interaction between networks while the unidirectional arrows, superficial one-way interaction, not likely to create any capital)

In a social capital context, civic or communal virtue is most powerful when embedded in a network of reciprocal social relations. The responses of the adult FGD participants indicated social interactions which were reciprocal at various levels ranging from family to religious societies and community leadership, and this is the basis for the interaction between the participants and their various linkages making possible the production and maintenance of social capital, which include communality and solidarity (Tzanakis, 2013). This implies that resources that constitute social capital are in social relationships not individuals, so in effect the resources tapped by the adult participants are products of their interactions with various associations within the community.

To further support this phenomenon of generational shift, Ephraim (2013) showed that children and youths aged between 13 and 30 years constitute Africa's heaviest users of social media (Ephraim, 2013). This age group also constitutes the Generation Y⁸⁰ (people born between 1978 and 1989) which has been characterized as self-expressive, group-oriented, global and technology-dependent (Tulgan, 2016). Generational differences based on technological development, expansion and influences have been described by several authors, causing a generation gap and value-conflict with the adult world (Halyal & Mallappa, 1986; Patil, 2014; Tulgan, 2016). Generational shift has been described as a powerful lens through which to understand the attitudinal and sociological diversities among the youths of today's world (Tulgan, 2016). The influence of generation gap has not been previously described in relation to genomic

⁸⁰ Studies have identified generational differences based on technological advancements and influences. The generational groups identified include a) Baby Boomers (born between 1946 and 1964); b) Generation X (born between 1965 and 1980); c) Generation Y (born between 1981 and 2000); and d) Generation Z or Millennium (born between 2000 and present). The younger generations of Y and Z are increasingly relying on personal technological devices such as mobile phones to define themselves and create social circles apart from their families, and changing the way they communicate with their parents and friends. They are more connected than ever, but also far more independent. The details of the differences in these generations are outlined in the works of Patil (2014) and Bruce Tulgan (2016).

research participation. From my data, this age-related shift, consequent upon exposure to ‘new’ technologies influenced the youths’ decisions and shaped the foundation of their willingness to participate in genomic research.

Relative solidarity model: This discordance has significant implications for community engagement in sub-Saharan Africa. First it means that researchers must consider the views of different groups in communities as their perceptions and attitudes may differ based on their individual preferences and convictions. Second, to assume that all people within a community will demonstrate similar ethico-social views may result in conflicts and disruption during conduct of research. Therefore, to forestall ethical conflicts in the community engagement process for biobanking research there needs to be a model that will embrace this phenomenon of ‘generational shift’ without disrupting the existing communitarian values and structure.

According to Callahan (Daniel Callahan, 2012), the first set of questions to be raised about any ethical problem should focus on its social meaning, implications and context even in those scenarios which affect individuals only. Thus, to accommodate the position of the youths, I propose a model of ‘relative solidarity’ within the ethical framework of responsive communitarianism (Ogunrin, Woolfall, Gabbay, & Frith, 2018). This model is a move for recognition of individual’s capacity for agency and rationality without rescinding their respect for communal values. This allows individuals to situate their personal opinions and preferences within the sphere of communal values thus embracing solidarity which is relative in that it considers the well-being of others without sacrificing individual choices, thus showing concern for other community members to benefit from the genomic research. This is consistent with brotherhood, togetherness and communality.

To explain why I conceptualized the relative solidarity model within the ethical framework of responsive communitarianism, as opposed to authoritarian communitarianism, I need to distinguish between these two types of communitarianism. Authoritarian communitarianism in seeking the common good among societies focuses on conformity and conventionalism, authoritarian power structure, rigid stratification, and discriminatory practices against minorities and women, with enforcement of compliance to communal values through coercion and manipulation (Heberer, 2009). Consequently, authoritarian communitarianism rigidly enforces communal values on people without democratic dialogue and careful evaluation of what is good and bad about tradition, thereby causing severe restrictions on personal freedom, political and civil rights. On the other hand, responsive communitarianism's main thesis is that people face a conflicting situation of two major sources of normativity: that of the common good and that of autonomy and rights, neither of which in principle should take precedence over the other (Etzioni, 2011). My model of relative solidarity aligns with this principle, but in addition advocates respect for communal values without ignoring personal convictions in the furtherance of the common good. Relative solidarity will thus allow for fruitful dialogue at community town hall meetings, reduce tension that may arise from contrasting views among community members, and facilitate early resolution of conflicting ethical issues in genomic research participation. See Table 8 for the differences between communal and relative solidarity.

A delicate balance between liberty and social order, and between individual rights and social responsibilities is required to prevent ethical conflicts which may arise from this phenomenon of generational shift. The model of relative solidarity, which I propose, allows for expression of personal rights and preferences in furthering the common good, therefore is not compatible with authoritarian communitarianism. However, it aligns with responsive

communitarianism that allows furthering of the common good without disregarding individuals' preferences.

Table 8. Differences between communal and relative solidarity

| Goals | Communal solidarity | Relative solidarity |
|--------------------|---|--|
| Common good | Pursuance is based on shared understanding of society and its goals (communal values) | Pursuance is based on personal convictions and communal values |
| Obligation | There is a strong sense of obligation to communal values | Limited obligation to those communal values that contradict personal convictions. |
| Cost | Willingness to bear costs on behalf of others towards achieving the common good | Willingness to bear costs on behalf of others towards achieving the common good, if these cohere with personal convictions |

So, the model of relative solidarity may offer meeting point for communitarianism and liberal individualism, especially when dealing with ethical issues of genomic research and biobanking. This model differs from relational autonomy that emphasizes autonomy as capacity of rational individuals to make un-coerced informed decisions without, at the same time, abrogating their obligations to other people as well as the particular conditions at a given time (Gauthier, 2000). Relational autonomy is simply addition of communal values to a set of liberal values. Therefore, it is a modification of individual liberalism that sees individuals' identities, interests, ends, and beliefs as fundamentally dynamic, continually constructed and reconstructed in dialogic processes with other people as well as with our traditions and with history (Walter &

Ross, 2014). Though it is grounded on the social nature of people's lives, it remains a conception of autonomy. I believe this approach does not make it an adequate communitarian ethic.

Relative solidarity, on the other hand, is a modification of a key communal value therefore is not outside the scope of communitarian ethics. A major difference between relative solidarity and relational autonomy is that relative solidarity allows for personal convictions over communal beliefs to further the common good while relational autonomy allows individuals to bring their autonomous desires or choices to fruition, thus allowing autonomy to flourish. This implies that individual convictions within the framework of relative solidarity must align with achieving the common good, focused on welfare of everyone in the community. It is not individualistic, rather it questions traditionalism and beliefs that militate against community advancement and development. Therefore, in the context of genomic research, relative solidarity motivates individuals to accept costs or risks of the research to further the common good based on personal convictions of the benefits of the research to the community and individuals.

9.3 Conclusion

In this chapter, I have discussed genomic literacy among prospective research participants and biomedical researchers, the factors that influenced the willingness of the potential research participants to participate in genomic research, and the discordant views. I integrated data with theory to describe the generational shift phenomenon and proposed the relative solidarity model to explain the divergent views. In the next chapter, I discussed the consent process in genomic research, focusing on the understanding of my study participants on what constitutes informed consent, type of consent process they preferred for biobanking research and level of preparedness of the biomedical researchers for genomic research.

CHAPTER 10

Consent Process in Genomic Research

'Ethical research does not require a guarantee of no harm, it requires investigators to exercise due diligence' (Tomlinson, 2013)

10.1 Introduction

In this chapter, I discuss my data on the responses of the potential research participants and the biomedical researchers on what they understand by informed consent and the type of consent model they preferred for biobanking. In addition, because of the influence of researchers' genomic literacy and ethical competence on the consent process vis-à-vis the aptitude to educate prospective research participants or to disclose information on genomic research and conduct genomic research in an ethically acceptable manner, I explore and discuss the level of preparedness of the biomedical researchers as well. Also, I consider the discordant responses and deviant cases among the potential research participants and biomedical researchers, examine the possible emerging changes in potential research participants' perceptions and attitude to genomic research and biobanking, and develop theories to explain the disparities in their responses. As discussed in the previous chapter, I established the *endoxa*⁸¹, by exploring how my study participants, the community members and biomedical researchers, understood the concept of informed consent.

10.2 Study participants' understanding of Informed Consent

Majority of the potential research participants opined that informed consent is, in the words of one of the potential research participants, *Eugenia*,

⁸¹ The concept of 'endoxa' was discussed under Symbiotic Empirical Ethics in chapter five, p.127.

‘when the researcher genuinely disclosed what he wants to do, the possible risks and benefits, type of sample he wants to collect, and agrees to feedback the results of the tests, and they (we) agree to donate their (our) samples’.

A few of them added that informed consent included the approval by the community leadership, especially the community ruler. The research participants were unable to define how much detail about the research is needed for consent to be informed because of the limitation in their knowledge of genomic research. They emphasized that they would like to know the benefits and the possible harms before giving their informed consent.

For the biomedical researchers, the thematic analysis produced four categories covering the components of informed consent, namely: *disclosure (partial or total), comprehension of information, voluntariness, and competence.*

10.2.1 Disclosure

Most of the biomedical researchers opined that for consent to be informed there must be full disclosure of what research entails, vis-à-vis what the research is about, what is expected of the participant, the specimens to be collected, the possible risks, the intended benefits, and what tests will be conducted on samples. Two of the biomedical researchers expressed their views in this manner,

‘Informed consent means that there is prior information before the consent comes in. You inform the participant about what you want to do, how you want to do it, what are the benefits, what are the risks; the benefits to the individuals, to the researchers, community. You also let them know any risks that may come into play while doing the research. You let them know that if there are other things that you will be doing. Those that want to participate will give their consent’ **Dr Mole,**

and

'Informed consent means having explained the important aspect of a research to a participant with clear understanding of the Pros and Cons, the participant is now at freewill or liberty to make a decision whether to participate or not, that is my own opinion of informed consent' Dr Moon.

They however expressed concern about how to effectively communicate the meaning and details of genomic research to the participants. This is related to genomic health literacy which I discussed in the earlier chapter. The researchers emphasized the need to communicate genomics to the participants in the language the community understands, implying the use of terminologies which are linguistically appropriate.

Three (two males and one female) of the researchers felt that partial disclosure, with emphasis on important aspects of the research like the benefits and risks, could be an acceptable option. They preferred this option because of the complexity of genomic research and its terminologies. They identified the important aspects of the research to be disclosed as the purpose of research, the possible risks to participants, the benefits, and what was expected of the participants.

10.2.2 Comprehension

Despite the disparity in views expressed on disclosure of research details, all the biomedical researchers agreed that participants must comprehend whatever information is disclosed. They agreed that the consent process is a two-way communication process, a dialogue between the researcher and the participant, and as such participants must be allowed to ask questions and seek clarifications before consenting to participate.

‘So, you can break down the protocol to the level of JSS 3 student. That means that people should be able to understand. It should be simple enough, need to break things into little ‘little’ (this 2nd little is for emphasis) segments for easy understanding’ Dr Matt

‘In relation to the participant, informed consent has to do with a total understanding of what the research is all about’ Dr Sugar.

The understanding of research details by research participants is vital because miscomprehension of information during the consenting process exposes research participants to harms, thus it is unethical (Krosin et al., 2006). Consent cannot be informed, if research participants cannot comprehend information about the research.

10.2.3 Voluntariness

There was also agreement on the importance of the voluntariness of participation. Some of them suggested that consent should be obtained in the presence of a witness to attest to voluntariness, as exemplified by the view of this respondent,

‘And then when the participant gives his or her consent, it should be with complete understanding and the presence of a witness or two to complete the whole picture’ Dr Sugar.

A few of the researchers mentioned the need to emphasize to the participants that they are at liberty to decline or withdraw at any time after consenting to participate without penalty, ill-treatment or discrimination. A biomedical researcher said,

‘If they decline, you also need to let them know that it is not to their detriment. Their refusal will not make you have any bias towards them’ Dr Mendy.

10.2.4 Competence

In terms of competence, that is capacity of the research participant to give consent, most of the biomedical researchers believed that the level of education of the participants has a significant impact on their competence to consent to genomic research participation. They talked about those with formal education being in a better position to understand the concept of genomic research. They however stated that the community engagement process should take care of this gap with the possible opportunity to talk to the community through intermediaries who would interpret in a language the people can understand.

On the other hand, the adult male FG participants did not see level of education as a barrier to competence in the consenting process. One of the adult males stressed that majority of community members were educated, although their literacy might not be the western, orthodox education but that they have acceptable intelligence for communal interaction, with capacity for decision-making. The adult male said,

‘you cannot cajole the people, our people are intelligent, they would understand what you say, so let them know what they will gain’ Barnaby.

Minority of the adult female participants opined that consent should be assumed if the research was conducted in the research institution like the hospital. For example, one of the female adult respondents believed that research participants were under obligation to donate bio-specimens because they attended the hospital; she said,

‘Once you are attending the clinic you have to give your sample. As long as one is attending the clinic one has to donate the blood’ Clara.

This view raises ethical issues of participants perceiving themselves as vulnerable, especially with the prevailing paternalism among clinicians who sometimes are clinician-researchers.

10.3 Consenting for biobanking

I discuss the themes on consent for biobanking research participation under two sections, first is storage and export of biological samples⁸² and, second, consent type preference among the potential research participants and biomedical researchers.

10.3.1 Storage and export of bio-specimens

There was consensus in the responses from the prospective research participants and the biomedical researchers on this theme. Based on their responses, I developed sub-themes along a continuum of levels of agreement to show the various grades of consent for storage and export, namely: a. Disagreement; b. Indecisive; and c. Full agreement.

10.3.1.1 Disagreement

Regarding storage, the prospective participants, mostly the male and female adults, said they would not agree to their samples being stored. Minority of the youths (both males and females) disagreed with storage of their bio-specimens. One of the adult females, when asked if she would agree, queried the interviewer while at the same time speaking for other members of the focus group,

‘why would the researcher want to store our blood samples? if we do not know what it would be used for, we would not agree, is it for ritual purposes (juju)?’ Elizabeth.

In the same vein, one of the adult males talked about fear and superstitious beliefs constituting barriers to storage of bio-specimens. He said,

⁸² The ethical issue of storage and export of bio-specimens was discussed in chapter two, section 2.3.4, p. 18.

'the issue of superstition and fear is always there. I will agree for immediate test but for storage and for export I just will not agree' Mackie.

Similarly, the community leaders and the health workers said the community members would not allow their blood or body parts donated for genomic research to be stored. One of the community elders emphatically stated that he would not allow his own blood samples to be stored, his words:

'they will discard you o, even me as a person I will not accept or agree to you collecting my blood sample for storage, once we know about it ahead of time, we will speak with the members of the community that this is what you want' Elder Jonah.

Two of the community elders however opined that the prospective research participants might agree if the community leadership convinced them of the purpose for storage, the benefit of the research, and the trustworthiness of the researcher. On the overall, the consensus was that the community members would not agree.

Majority of the biomedical researchers echoed the fact that the community would not agree to storage of their samples, except if the community leaders influenced their decisions to consent. The researchers felt that people would become suspicious and think that their samples would be used for ritual purposes. The researchers and the community leaders also felt that communicating the reasons for the storage and the intended benefits from biobanks would facilitate their consenting to storage of their bio-samples. The biomedical researchers agreed with the potential research participants that the community members would consent if they know the reasons for storage and export of their bio-specimens except for a few of the researchers who said that the potential research participants would agree to storage and export of their bio-samples

even if they were unaware of the reasons. I discuss these discordant views under ‘Full Agreement’ theme below.

For export of bio-samples, there was also consensus in the responses of the various groups of participants. The potential research participants disagreed with the export of their samples to laboratories or facilities outside the country for analysis. The same views were expressed by the community leaders, community health workers and the researchers. The factors that influenced their non-consenting to export included lack of knowledge of and trust in foreign analysts, superstitious beliefs related to use of bio-specimens for rituals (money-making) or voodoo practices, and lack of communal acceptance. One of the adult males opined that

‘For the larger community, people would not agree to export of their samples, it can raise a scandal except you talk to organisations (church, mosque) that will understand what you want to do then they will agree. If something happens, then people will come to you and say this thing happening to you is because of where your sample was taken to’

Taylor.

A female youth expressed her views this way,

‘I will not accept. I need to know the people that will work on my samples, I will not allow my samples to be taken abroad. There are so many factors, apart from superstition, I need to know the people, they must be credible’ **Rita.**

10.3.1.2 Indecisive

A few of the youths were indecisive about whether to agree or disagree to storage or export of their bio-samples. They felt they might agree depending on whether they were fully informed of where the specimens would be stored or exported, who would be analyzing them,

and if the storage or export of their samples would cost them nothing, and the level of trust they have in the researcher. Their decisions to disagree was based on fear, superstitious beliefs and mistrust of the researcher.

I illustrate the indecisiveness of one of the youths with this quote;

‘I may agree, and I may not agree. The reason why I said I might agree is that we are in the hospital and they take people’s blood and they take it out of the country, it is their duty. If I were to transport my sample there it will be very expensive, and I don’t have the money so they are the ones taking care of that, that is okay, but on the other hand I just need to be very careful because at the hospital they even take people’s blood, placenta do (for) rituals’ Anne.

There was no indecisive male or female adult respondent, that is none of the adult FG participants demonstrated ambivalence or unsureness in their responses. They either agreed or disagreed to storage and/or export of their bio-samples.

10.3.1.3 Full agreement

Discordant views on storage and export of bio-specimens: Among the potential research participants, discordant views on storage and export were expressed by few adult males and females (three adult females and five adult males) and eight youths (three females and five males) who agreed to both storage and export. They agreed to storage and export because of the benefits of early detection of predisposition to diseases, advantage of ‘double’ individual benefits implying doing test without costs and knowing their genomic test status, the trust in the researcher and the research institution, and advantages for future beneficiaries. Some of the youths who agreed to storage specified the duration for which they would want their samples stored, insisting that they would only allow storage for several weeks. For example, one of the

youths in this category said she would agree if the duration of storage will not exceed three weeks, in her words,

‘For storage for me if it is 2 weeks or 3 weeks but involving five years I cannot agree’

Jane,

and that she would not agree to storage for years or indefinitely. Among these youths, the reasons given for consenting to storage for a short duration included the need to perform tests on the specimens in laboratories outside the community, if it becomes necessary to do further tests, and in the event of errors in the initial tests such that there is need for repeat. Below are some quotes from the respondents to support this theme:

‘I will agree but it depends on the person or the organisation that is interested in collecting my blood, it depends on whether it will benefit me or for instance I have to pay money to repeat test if there is a mistake’ **Wood**

‘as long as it will not cause another blood, then you are giving me a double benefit, so storage is acceptable’ **Wilmot.**

Nine of the thirty biomedical researchers believed the potential research participants would agree to storage and export in contrast to the opinions of the community leaders, community health workers and the potential research participants. These researchers based their opinions on previous experience with community-based genetic research that involved collection and export of blood samples, and if the potential research participants were informed of the perceived benefits that they would receive from the export and further analysis of their bio-samples like getting feedback of results. Here are their responses:

*'From my own experience, I think there is a possibility that most people will agree because what we noticed is that most people are ready to have their samples checked. When you talk about storing it up, I think they will agree to have samples taken, stored up for a later check or for another research if they are going to have result or a preliminary result from that sample. And if you let them know the effects and the benefits of the research, they will be interested in participating in the research, by giving their samples for such research'. **Dr Matt***

*'They encourage it (storage and export), from my experience, they don't only allow, they encourage it because our people are aware of the limitations of our health care' **Dr Monty***

*'Many Nigerians once they feel safe enough to give their samples may not be bothered about storing them or taking them out of the country. Once Nigerians give, they give' **Dr Sugar***

On the overall, fear of unethical use of bio-specimens, superstitious beliefs and mistrust were important factors based on the narratives of the respondents. Furthermore, the decision to allow storage and export of bio-specimens may be facilitated if the potential research participants are informed of details of storage and export, that is where samples are kept, who is responsible for ensuring safety and confidentiality of their bio-samples, duration of storage, and what would happen to the samples, including which country and identity of foreign scientists their samples would be exported to. Another facilitator is the effective communication and cultural integration of the research through the community engagement process. Details of and reasons for the discordant views are presented in Tables 9 and 10.

An important peculiarity regarding genomic research in sub-Saharan Africa is that informed consent is complicated because it involves obtaining consent for collection, storage and sometimes export of large numbers of samples from low-income African to high-income developed countries for better storage facilities, but it is hoped that with bio-banks being established in several low-income countries including Nigeria, the export for storage will be a thing of the past. A typical example of exporting samples for storage in a developed country is the Malaria Genomic Epidemiology Network (MalariaGen) with approximately 100,000 samples from children affected with severe malaria and unaffected 'controls' collected in sub-Saharan west African countries like Ghana and exported to the United States (Tindana et al., 2012).

The opinions of bio-specimen donors on storage and export of their samples are important to forestall any potential ethical conflict. For example, a cross-sectional survey on views of Egyptian patients (though Egypt is not a sub-Saharan African country) on collection, storage and use of their blood samples for future research revealed that 41.8% and 37.2% of them were favourably disposed to export of samples to Europe and USA respectively but on the other hand, a significant percentage (62%) did not object to export of samples to other Arab countries (Abou-Zeid et al., 2010). On the other hand, the earlier mentioned Nigerian qualitative study on knowledge and attitudes to biobanking among lay persons showed that majority of respondents agreed to broad consenting and exporting and sharing of their samples for genomic research provided that the research on the donated samples would not contradict their religious beliefs (Igbe & Adebamowo, 2012).

10.4 Preference for consent type

There is debate over what type of consent meets high ethical standards for genomic research, despite an appreciable load of publications on the subject. Several models of informed

consent have been described in the literature, and these include broad, general, presumed, re-consent, tiered, delegated trustee, third party oversight and dynamic consenting. The major themes based on the responses of the biomedical researchers and potential research participants were labelled using the existing consent models which best described their preferences, and include:

- a. Blanket consent
- b. Re-consenting
- c. Broad or General consent
- d. Presumed consenting
- e. Third-party oversight/Delegated consent

The potential research participants and the biomedical researchers agreed that informed consent must be obtained before participation in genomic research, but there was no consensus among the research participants on what type of consent model was acceptable.

10.4.1 Preferred consent types for genomic research

10.4.1.1 Blanket consent

Blanket consent is a process by which individuals donate their samples without any restriction (Wendler, 2013). Many people view broad and blanket consent to be similar and use terms interchangeably but they are not the same (Beskow et al., 2014, 2010; McGuire & Beskow, 2010; Steinsbekk et al., 2013). Most of the biomedical researchers agreed that blanket consent, with a caveat that there is possibility for future use of bio-specimens, is acceptable for genomic research. This type of consent ignores the fact that samples may be re-used for studies that conflict with individual's fundamental values (Tomlinson, 2013).

One of the biomedical researchers put it this way:

'Many Nigerians once they feel safe enough to give their samples may not be bothered.

Once Nigerians give, they give' Dr Sugar

One of the researchers with experience in community genetics research opined that 'once they gave their blood samples, then they gave without attaching conditions to it' and would not ask about the outcome of the research.

'Once they have given their samples, they don't care what you do with it, but I think the onus lies on the researcher to stick to terms of reference. But most people, once they give the sample, they forget it and continue their life, in fact they don't even care if you come back to tell them the results of your findings' Dr Shaw

10.4.1.2 Re-consent

This demands that donors are informed, and are required to consent to the current study and then subsequently to each future research study involving the use of their samples and information (Ludman et al., 2010; Mee et al., 2013; Steinsbekk & Solberg, 2011). Here the researcher goes back to obtain consent from research participants. The main reason given for re-consenting is if secondary use of samples would cause harm to the participants.

'Yes, we need to go back. It is necessary to go back. From the onset, if we know that there is a need to go outside the test(s) that we specified initially, we need to seek the consent again' Dr Stone

'If am to give you, an ideal answer, the answer would be for you to go back. That's the ideal answer but more practical answer would be just to run the test and inform the individual later, if it's not going to harm the person' Dr Steel

10.4.1.3 Broad or General consent

Broad or general consent refers to a process by which individuals donate their samples for a broad range of future studies, subject to specified restrictions (Wendler, 2013). For example, insisting on ethics committee approval before sample re-use especially if there are perceived risks. This type of consent requires donors to actively consent once for the current study and all future research involving the general use of their samples and information (other terminologies include open and generic) (Haga & Beskow, 2008; van Schalkwyk et al., 2012).

'May not be always necessary to seek another consent but when it involves a key issue or has an important effect especially negative or positive effect on the community, then the researcher may have to go back' **Dr Mellow**

One of them used the surgical consent obtained pre-operatively in the clinical setting to illustrate this, in which the patient consents to 'leave the surgery to the discretion of the surgeon in case of any eventualities' as exemplified by the views of this researcher:

'Well in that case, it is like taking consent for surgery from patients. The consent is designed in such a way that any other necessary procedure apart from the one that is known is consented to. I just think that this probably could be applied in this case especially since you are keeping the sample' **Dr Stephanie**

10.4.1.4 Presumed

Consent is presumed when donors allow use of their samples and information for all research unless they actively choose to opt out (Borovečki et al., 2014; Caenazzo, Tozzo, & Pegoraro, 2013; Chima, 2013; Report, Committee, & Session, 2007; World Health Organisation, 2002). Some of them also opined that this model of presumed consent may not be acceptable to

most potential research participants except with the intervention of the community leaders, or among those who are literate, or if there is high level of trust in the researcher and/or the institution.

This biomedical researcher implied presumed consent when he said,

'I think that if the participant has consented that the sample should be kept, by that same token, the person is also agreeing that further study could be done on the sample. As long as it is kept confidential and then unauthorized access is not permitted' **Dr Saint.**

10.4.1.5 Third party oversight

This implies that donors can actively consent to a general, broad or other model, but an ethics board must approve the study before the commencement of research using stored samples and information. This approach is emerging as a common component of biobanking governance schemes (Auray-Blais & Patenaude, 2006; Yassin et al., 2010). Two of the researchers said that the ethics committee could play a role in consenting for further tests on donated samples to avoid the problems of re-consenting or tier consenting. This is similar to the '*third party oversight*' model and delegated trustee. In **delegated trustee**, donors can transfer consent to a trustee who is at arms-distance length from the biobank and consents on behalf of donors (Joly, Dalpé, So, & Birko, 2015; Master & Resnik, 2013).

'And the research ethics board can be duly informed that this issue came up, this research for which you gave clearance, this is what our intentions are again. I think the regulatory body can stand in and say that there is no problem and go ahead. Rather than getting back to the people' **Dr Mills.**

10.4.1.6 Dynamic consent

This involves giving a role to communities' consultation as part of decision-making process, a model termed 'active citizenship'. It is a patient or donor-centered approach with

mechanisms of governance engendered through information technology (IT) solutions to allow participants to engage as much as they choose and to alter their consent choices over time (Kaye et al., 2014). This approach improves public trust, limits participants' withdrawal from research, overcome perennial issue of consent form length and comprehension, improve transparency and accountability in research process through continuous contact with patients. This allows researchers to gather phenotypical information, reduce research biases and by using an epigenetic model, the burden of social and environmental effects on health become lighter. It however has the setbacks of greater management costs, and the possible risk of imposing ethical principles derived from theories detached from empirical data without considering citizens' thoughts is always around the corner (D'Abramo, 2015; D'Abramo, Schildmann, & Vollmann, 2015; Steinsbekk et al., 2013). One of the researchers suggested a *dynamic consent model* with use of social media-related application on a mobile phone. But he however felt it might not be appropriate and effective in a developing country like Nigeria with incessant electrical power disruption, the financial and economic implications and issues of ensuring confidentiality of data with mobile phone use.

'There is something we call bulk SMS now. If you have your patient's record, you can actually reach them via their numbers. You can reach the ones that you think are eligible for the new research. You can send out bulk SMS or call them to obtain further consent. It depends on if the other person (that is the individual) is willing to do that and if you are able to get another set of consent and the ethical committee said go ahead to do it'

Dr Misty

10.4.2 Discordant views on consent preference

10.4.2.1 Type of consent

On the side of the potential research participants, the community elders and the community health workers, there was discordance of opinions as majority of the adult respondents agreed to *blanket consent* whereas the community elders and community health workers said that the community members would not agree to blanket consenting but would prefer re-consenting. The youths preferred specific consent with re-consenting model. Details of the discordant views are stated in Table 9.

There was consensus in the responses of the community leaders and the community health workers, as both agreed that the community members would not agree to blanket or broad consenting but they would prefer *re-consenting*. They identified the barriers to blanket consent model to include fear of unethical use of bio-specimens (like using for rituals), mistrust, and not thinking that the research is beneficial. The community leaders and the health workers however opined that the intervention of community leadership may facilitate the acceptance of the broad and blanket consent models. The community leaders would have to assure the people of the integrity and competence of the researcher to gain their trust and cooperation.

Flora: *He must have a reason, no need for re-consenting. The blood is with him. He is looking for something, he is free to conduct further test*

Felicitas: *You tell them there is possibility of coming back*

Elder James: *It is difficult to get them to agree to storage and re-use, but if the king approves of the research then they are assured that that they are in good hands, that is when they would agree to their blood being used for other research.*

10.4.2.2 Community approval versus community consent

The majority view among the researchers was supported by one of the community elders and some of the focus group participants who opined that individuals are free to decide whether to participate or not because the community ruler's approval does not constitute consent.

'the Oba (community ruler) does not give consent for the people. The people must still give their consent' **Elder Johnson**

'(That is) Correct, the Oba (community ruler) does not give consent for the people, the people must give their individual consent, the people still have the power of choice'

Mackie

Although there was consensus among majority of the biomedical researchers that individual members of the community must give individual informed consent despite the community approval, there were discordant views from a few (six out of the 30 researchers) who said that once the community elders approved the conduct of a research, the community members would agree to participate because of the respect they have for the constituted authority but that does not preclude obtaining informed consent which, according to them, is now a formality. This latter group of biomedical researchers felt that potential research participants would not bother considering the possible risks and benefits once the community leaders have permitted the research because of the trust and confidence in the 'gatekeeping' ability of the community leaders. So, in effect, this group of biomedical researchers believed that potential research participants would agree to participate in genomic research because they respected the community leaders and they trusted the leaders to vet the research and confirm its safety before approving it.

In addition, one of the community leaders stressed that the approval of the community ruler (the king) is perceived as ‘community consent’ by the members of the community. As it is the traditional practice and cultural norm, the community will comply with directives from the king rather than do otherwise irrespective of their personal opinions or beliefs. But the responses among the youths were contrary to this.

10.4.2.3 Feedback of results as a condition for consent

An incidental finding⁸³, also a discordant view, from my data was the feedback of results which was talked about by the potential research participants as part of informed consent but was not considered by most of the biomedical researchers as part of the consent process. An adult female and male youth FG participants stressed that being assured of feedback of results was a condition for their consenting to participate in genomic research:

Flora: *‘I am okay with my blood being stored, the result is what we need. Life is in the blood, he cannot just take our blood, we need to know the result’*

Major: *‘I want to assure you if you come to me for my blood sample and bring out the result, I can assure you, I will agree’*

All the potential research participants, irrespective of their ages and gender, talked about considering feedback of results of genomic test carried out on their samples before deciding to participate in genomic research. They said that they were keen on the results even if they were likely to develop a disease that has no available treatment. For example, during one of the focus group sessions for the adult females, they expressed their views together as a group;

⁸³ An incidental finding is an observation of potential significance unexpectedly discovered in research participants in the course of conducting the research and unrelated to the purpose of the study (Wolf et al, 2008)

Delilah, Dorcas, Deborah, Diana: *'Yes, (all agree) we desire result of the tests even if there is no treatment'*

Research on willingness and attitudes of the public to genomic research has consistently showed that individuals would like feedback on their results ((Barchi, Matlhagela, Jones, Kebaabetswe, & Merz, 2015; Marodin, França, Rocha, & Campos, 2012; Middleton et al., 2013; Thornton, 2009). An earlier Nigerian study showed that participants would like to receive feedback of their genomic tests' results (Igbe & Adebamowo, 2012). Similarly, Ahram *et al* studied the factors that influenced public participation in biobanking among Jordanians and reported that feedback of results was the most important influential factor in the participants' decision to become biobank donors (Ahram et al., 2014).

Whether researchers in Nigeria and other sub-Saharan African countries are well-prepared to communicate results of genomic test to prospective participants remains uncertain because there is no study, to the best of my knowledge, that has examined the level of genomic health literacy among them except our study which is awaiting publication (Ogunrin, Taiwo, & Frith, 2018). Also, communicating genetic information requires skills in general counselling (Hansson, 2011). Despite this likely uncertainty about the preparedness of researchers in sub-Saharan Africa to communicate genomic test results, ethical guidelines from seven countries, namely Botswana, Cameroon, Ethiopia, Rwanda, Malawi, Sudan and Uganda specifically referred to return of genetic results. There is also lack of consensus on strategies and approach of feedback, for example in Ethiopia and Rwanda, individual research results should not be given to family members or third parties without written permission from the individual, and in Ethiopia approval by the national REC is an additional requirement, while in Malawi, return of results would be determined by the investigator based on the sensitivity and specificity of the test and if participants consented to

disclosure of results, and this should be done by a genetic counsellor. In Cameroon and Botswana, individual consent is required, but in Cameroon genetic counselling and disclosure of data sharing are additional requirements (Jantina de Vries et al., 2017).

There are different standards and approaches among various biobanks and genomic research groups on feedback of results to donors of bio-specimens because there is no consensus on when, and under what conditions, it is appropriate to feedback results to participants. For example, the International HapMap Project researchers would not feedback results to prospective donors because of the absence of individual identifiers (Rotimi et al., 2007). This is similar to what obtains with the UK Biobank project where participants know that they will receive no feedback at any stage because they donated their bio-specimens based on trust and altruism, not for a health-check (Thornton, 2009). There have been suggestions from African scientists to follow this approach because of the complexities that accompany feedback of results. Ramsay *et al* suggested avoiding an expectation of health-related feedback to individuals and discussing this with participants at the outset of the project, and research findings that may impact the participants' health and require medical care should be referred to the national health system infrastructure (Ramsay, de Vries, Soodyall, Norris, Sankoh, et al., 2014).

Studies from most European countries however showed that prospective research participants would like feedback on the results of genomic testing (Gaskell et al., 2013) though some European biobanks are not practicing it. Failure to feedback results is often considered unethical when doing research with indigenous and developing communities possibly because of the existing health and socio-economic inequalities that make them vulnerable to exploitation. For example, conducting research among the indigenous Australian aboriginal communities with little or no feedback to them was condemned as exploitation (Gower, 2015). Despite the fact that the

public will like feedback of their results, empirical data on the attitudes, values and beliefs of potential research participants about receiving the results from genomic studies as opposed to genetic is still limited (Middleton et al., 2013). However, the right of individuals not to be informed of results of genomic research should however be respected. If the result of the research however has significant health implication on other members of the individual's family, the decision to feedback the family members will be dependent on several factors including whether they had initially consented to receive such information, public health grounds of utilitarianism (the benefit for the greater good of the majority) especially if there are treatment or prevention modalities, financial considerations and communication logistics.

Table 9 - Discordant responses among my study participants

| Ethical Issues | Potential research participants | | Community health workers | Community elders | Biomedical Researchers |
|--|---|---|---|---|--|
| | Adults | Youths | | | |
| Influence of communal values on genomic research participation | Based on traditional communal values | Based on personal convictions | Based on respect for communal values | Based on respect for communal values | Community would participate based on communal values |
| Type of consent process preferred | Majority preferred blanket consent | Preferred specific consent with re-consenting model. | Community would prefer re-consenting | Community would prefer re-consenting except the community ruler intervened for blanket consent | Majority preferred blanket consent. Minority opted for re-consenting. |
| Feedback of results as part of consent | Feedback of results talked about as part of informed consent | Feedback of results talked about as part of informed consent | Feedback of result is important | Feedback of result is important | Did not talk about feedback of results as part of informed consent |
| Community approval versus community consent | Community approval of research is NOT consent – minority view | Community approval of research is NOT consent – majority view | Community approval of research is NOT consent but community would agree if the elders agree | Community approval is NOT consent – majority. Deviant case 1 out of 4 – community would consent if the community ruler approved conduct of research | Community approval of research is NOT consent – majority view Deviant cases 6 out of 30- opined that community elders' approval constitute consent as the community members would agree to participate because of the respect they have for the constituted authority |
| Storage and export | Majority disagreed but 6 (agreed) deviant cases of 23 adults | Majority disagreed but 8 deviant cases out of 27 youths | Community would disagree | Community would disagree | Community would disagree but 9 deviant cases out of 30 |

Table 10 Reasons for decision on consent for storage and export of bio-specimens among study respondents

| Prospective research participants | | Biomedical Researchers | |
|--|--|---|--|
| <i>Agreed with storage and export</i> | Disagreed with storage and export | Agreed that community would consent | Disagreed that community would consent |
| Benefits of predicting and knowing future predisposition to diseases (feedback of results) | Lack of trust in researcher and research institution | Full disclosure of the perceived benefits of storage and further analysis | Ignorance of the benefits of exporting bio-specimens for further analysis |
| Benefits of storing and exporting bio-samples, and doing test without cost | Superstitious beliefs and myths in use of blood and body parts for rituals | Based on personal previous experiences in community-based genetic research with bio-specimens | Superstitious beliefs and myths in use of blood and body parts for rituals |
| Trust in the researcher and research institution | Lack of knowledge of foreign analysts | Trust in the researcher and research institution | Lack of agreement and support from community leadership |
| Advantages to future beneficiaries of research | Lack of communal acceptance | Health-related inducements like medical check-up (blood pressure and sugar checks) | |
| Putting a time limit on storage of samples | Non-disclosure of where samples would be stored or who would be doing the analysis | Timely feedback of results of genomic tests | |

10.6 Preparedness of the researcher

Despite the importance of scientific competence and ethical preparedness of biomedical researchers, few studies have investigated the readiness of biomedical researchers for genomic research. This may be related to the limitations of assessment of preparedness of biomedical researchers. For example, there is lack of globally acceptable, definitive parameters that can be used for determining preparedness. According to Vassy *et al*, preparedness cannot be based on self-reported attitudes and perceptions because they do not necessarily correlate with skills and behaviour (Vassy, Kort, & Green, 2015). Though it reflects understanding of genomics, objective assessment of genomic literacy might not adequately determine whether a researcher is prepared to carry out a genomic research. Since my thesis is concerned with ethical issues, it seems apt and relevant to assess the biomedical researchers' awareness of ethical guidelines for conduct of genomic research based on the main legal document that is used in their environment.

Therefore, I explored the ethical preparedness of the biomedical researchers for genomic research from their responses to questions that assessed their awareness of and whether the Nigerian National Code of Health Research Ethics⁸⁴ addresses the conduct of genomic research, and their genomic research literacy. The latter has been discussed in the preceding chapter. The analysis of their responses to questions on awareness of the National Code of Health Research Ethics, and if the Code addresses conduct of genomic research in Nigeria, yielded a continuum of degree of awareness:

- a. Theme A: Lack of awareness of Code and its limitation
- b. Theme B: Awareness of Code but lack awareness of limitation
- c. Theme C: Awareness of Code and its limitation

⁸⁴ The national Nigerian Code of Health Research Ethics was discussed in chapter five, section 5.6, p. 107.

10.6.1 Lack of awareness of Code and its limitation

Eighteen of the researchers were not aware of the National Code of Health Research Ethics therefore they could not comment on whether the Code addresses conduct of genomic research, hence lack knowledge of its limitations regarding ethical guidelines for conduct of biobanking in Nigeria. One of the researchers, in response to questioning during the interview, asked pensively, '*how many of us are aware of the code?*' (**Dr March**) implying low level of awareness of the code among researchers in the country. The details of the excerpt from the interview is as stated below:

***Interviewer:** Lastly, have you come across the Nigerian Code of Health Research Ethics before?*

***Dr March:** I have not heard about that. All I know is that each institution has ethical committee subject to a national one*

***Interviewer (cuts in):** Yes, there is the national one.*

***Dr March (responded with a question):** How many of us are aware of the code?*

10.6.2 Awareness of Code but not of limitation

Seven researchers were aware of the code but could not say if the code addressed the conduct of genomic research. Four of the seven heard of the code during preparations for postgraduate fellowship research because they were required to obtain ethics approval for their fellowship theses. Certification of successful completion of the informed consent course, an integral part of the code, is a pre-requisite for ethics approval. The remaining three knew about the code due to attendance at seminars on ethics of human subjects' research held in their institutions or through attending the ethics committee's meetings.

'I am aware. I got to know that because as a senior resident I was a frequent attendee to ethics and research committee of my teaching hospital and with the mentorship of my

trainers, I know quite a number of things that are involved and that is why from the national code, institution step it down to have their own local adaptation of such regulation, so am aware of research code.' **Dr Martin**

'Yes, I am aware. I heard about it when I was writing my research a couple of years ago. I was referred to the site to look at the inform consent format. I didn't read through the code before I got the informed consent section.' **Dr Soul**

However, often they could not ascertain the code's coverage of genomic research guideline because they had never read the whole code. Two researchers who had read it several years ago could not remember as they had not had opportunity for refresher courses or seminars. This dialogue illustrates this point.

Interviewer: *Have you heard of the Nigerian code of health research ethics before?*

Dr Mendy: *Yeah, I have heard about it because I had the opportunity to attend a workshop on ethics and research.*

Interviewer: *Have you read through it?*

Dr Mendy: *It's been long, but I can't remember again but I think I have a book on it, but I can't remember, and I have not attended a seminar recently.*

10.7.3 Awareness of Code and its limitation

Only five of the biomedical researchers knew of the code and said that the code did not adequately address ethical conduct of genomic research in Nigeria. Three of the five were the genetic researchers.

'Knowledge of medicine is getting more genomic, disease concept these days are now being linked to the genome whereby we look at disease not just as a morphological appearance. I am aware that the you cannot find guidelines on how to carry out genomic research in the code, especially when it comes to use of blood samples and genetic data'

Dr Mellow

'I don't think it addresses it very well, because I had opportunity to attend one workshop in Abuja on genetic research, that's about 3 years now. It was one of my supervisors that invited me.' **Dr Moon**

One of the two who were not involved in genetic research mentioned that the code addressed the issue of material transfer agreement (MTA).

'Also, I attended a seminar two or three years ago when we were starting the University. At the seminar, one of the things they taught us was the material transfer agreement which I think talks about transfer of specimens to other countries' **Dr Matt**

The three genetic researchers did not talk about the MTA. The biomedical researchers engaged in genetic research did not differ in level of awareness of the limitations of the national code to guide genomic research when compared with the two other researchers who were similarly aware of the code's limitations.

Our study demonstrated a low level of awareness of the country's ethical code among the researchers and little ethics support in terms of guidelines for these researchers. Advancements in genomic technology have produced ethical issues that must be addressed by researchers. Lack of adequate ethics training and preparedness places researchers in a position where they might be unable to effectively assess and resolve the ethical dilemmas presented to them (Zawati, Cohen,

Parry, Avard, & Syncox, 2015). This might result in the unethical conduct of research. When researchers are aware of inadequacies of existing national ethical guideline for conduct of genomic research, they can canvass for an update or revision of the code.

A Canadian qualitative study that explored healthcare professionals' knowledge, attitudes and perceptions of genomics showed that although their study participants have little knowledge about genomics, they cited the importance of and called for stringent regulatory oversight of genomic research to ensure public protection (Weir, Morin, Ries, & Castle, 2010). The findings of this study are similar to my finding regarding the poor knowledge of genomics. But in terms of awareness of the need for robust guideline for ethical conduct of genomic research, my findings differ because majority of my study participants were not aware whether the existing national code covered genomic research. The potential perils of unpreparedness include insufficient knowledge and expertise for communicating decisions of genomic testing to patients (Vassy et al., 2015).

10.7 Conclusion

In this chapter, I have discussed the understanding of informed consent among and consent type preference of the biomedical researchers, community leaders and the potential research participants. In addition, I discussed the views of the potential research participants on biobanking and how biomedical researchers perceived the response of research participants to storage and export of their bio-specimens, and appraised the level of preparedness of biomedical researchers for genomic research.

The discordant views identified from my data based on the responses of my study participants, that is the potential research participants, community leaders and biomedical researchers, constitute possible areas of ethical conflicts in conduct of genomic research. My

study demonstrated the lack of consensus between the adults, youths and community leaders on preferred consent type, though the biomedical researchers agreed with the adult FG discussants on choice of blanket consent. In addition, there were dissenting views among the three categories of respondents on equating community approval of research with community consent. The importance attached to feedback of results of genomic tests by the potential research participants in the consenting process did not reflect in the responses of most of the biomedical researchers. This is a significant observation in that it may negatively affect genomic research participation of individuals and communities. In the next chapter, I set out the circumstances and tell a story of the interactions or ‘networking’ between the community members and within the community on one hand, and between the community and the biomedical researchers on the other hand, towards initiation and establishment of community engagement processes.

CHAPTER 11

Community Connections, Communitarianism and Community Engagement

11.1 Introduction

Community engagement (CE) is an important aspect of ethical conduct of research especially when research is focused on ethnically or culturally distinct populations but the components of CE necessary for this engagement in the context of genomic research remains unclear (Tindana et al., 2015). Therefore, there has been a call for strategies for engaging communities in genomic studies in Africa so that communities can be informed and educated about genomics, and information can be exchanged between the research team and potential research participants about the research process over a period of time. When considering community engagement however, the important questions to ask include; what is community engagement? Why is the community engaged? Why would people want to be engaged? Who needs to be engaged? Who engages? When should we engage? How should communities be engaged? In the discussion of my themes I attempted to answer these questions.

11.2 Timing of community engagement

To answer the question on when to engage the community, most of the biomedical researchers agreed that community engagement should commence at the outset of the research by engaging the community leaders. A few however stated that community engagement should not be limited to the pre-commencement phase of research but the community should be engaged at every stage of the research, as exemplified by this biomedical researcher's comment,

'at every stage of research, there is a need to educate, train, talk, to the leaders' **Dr Mole.**

Irrespective of when it is done, all the biomedical researchers agreed that CE is needed to enhance the understanding of research goals and procedures especially with the complexities

involved in genomic research. They also felt it might serve as an avenue for feeding back findings to participants and communities. There was consensus between the views of biomedical researchers and potential research participants on when the community should be engaged. All the potential research participants, including the community elders, said that community engagement process should commence at the beginning of research because that is the most appropriate time to disclose information on the research.

'It is better at the beginning, you go to the ruler of the community, you cannot just jump into the community, so you tell him (that is the ruler), please I need your assistance'

Baylor

'Letting the people know about what you want to do is important, information matters, so let them know at the time you want to start' **Veronica**

'You know it will be difficult for them, for the people to accept your research, but if we (the community leaders) are the first to speak with them, it will not be difficult, so you need to let us know before you start your research' **Elder Jonah**

11.3 Themes for community engagement

The final coding of the responses from my study participants revealed the following themes:

- a. Effective communication
- b. Diversity of community gatekeeping
- c. Trust
- d. Cultural integration of research
- e. Community leadership role synonymous with 'local Ethics Committee' (in terms of oversight functions)

f. 'Spoiling the research field' – Conservation of the research setting

I discuss these themes as components of the four stages of proposed framework for community engagement I developed from my data (see Table 11). The four stages are i) Community approach; ii) Community interphase; iii) Community collaboration or integration; and iv) Post research cordiality.

Table 11 Four-stage proposed model for community engagement in genomic research

| | Stages | Themes |
|----|--------------------------|---|
| 1. | Community approach | Community leadership, Diversity of gatekeepers, Trust, Community leaders as 'local ethics committee', |
| 2. | Community interphase | Effective communication, Trust |
| 3. | Community integration | Effective communication, Cultural Integration, Trust |
| 4. | Post-research cordiality | Trust, Conservation of research field |

11.3.1 Community Approach

This is the initial and most crucial stage of the community engagement process. This is when the researcher contacts the community. The respondents thought it would be important that the research team contact the community leadership and that this is the unique determinant of success of community engagement. Also, all the respondents, both potential research participants and biomedical researchers, stressed the role played by the community elders and opinion leaders in the success of research in the community, emphasizing that this is even more important when it comes to genomic research. There was a consensus among all the biomedical researchers, the community rulers and elders, and the potential research participants on the proper and appropriate

community approach, contacting the community leadership. Three of the biomedical researchers (including one researcher who shared his personal experience of a previous community-based research) expressed their views as stated below:

‘One has to engage the political network – authority like Bale (chief), Obas (rulers), religious groups, the best way to get the people is through their leaders, this also helps to ensure openness and transparency’ **Dr Sandy**

‘What I mean by approach is that it is a community-based research. If you approach their community, first by talking to their community leaders. You approach the community leader first, try to brief him and his team, his council of elders what you are planning to do, how the research work will go, that is what I mean by community approach’ **Dr Song**

These comments stressed the importance of the community leadership as the focus of community approach, and the fact that engaging the community leaders would demonstrate transparency in research. Similarly, these quotes from one of the community elders and two focus group participants supported this assertion. The community elder volunteered to act as the bridge or link between the researcher and the community ruler (the king) to stress how important it is for the community ruler to be informed as a focus of community approach and this should be at the beginning of research.

‘Before you start, it’s important you should see the king. If you see him, you then tell him about it even if you’re not coming today. I will take you to see him or I should call him on phone that someone is coming to see him’. **Elder Jonah**

'We have the way we communicate, we have trusted leaders, if they (researchers) communicate to them (the community leaders), then they (researchers) have informed the people indirectly' Philemon

'They (referring to the researchers) need to interact with community leaders, then they (referring to the community leaders) will call the community people, then we are sure the research is genuine' Elizabeth

A major attribute of the community approach stage is that it creates community awareness of the research project. The researcher makes known the reason for his presence in the community by disclosing the details of the research to the community gatekeepers, the community ruler and elders. Awareness was defined by the respondents as *'knowing what is being planned by the researcher or research team and getting such information to them through their community leaders'*.

Approaching the community leadership is a demonstration of respect which has been identified as one of the four main goals for community involvement in research, with the other three being protection; empowerment; and partnership (Marsh, Kamuya, Rowa, Gikonyo, & Molyneux, 2008). These goals are especially important due to differences in social and cultural norms, values, goals, resources and technological understanding between researchers and typical participant communities. This is consistent with the ethical principle of respect for persons, but in this case respect for the community. It is a demonstration of respect for the people's culture and a way of seeking their consent, especially when one considers the fact that the conduct of research will constitute a disruption to their regular day-to-day social and economic activities for the period it lasts.

The community ruler represents the whole community, and they are chosen by the community. The community ruler is respected by the community and perceived as a representative of the gods, serving as an intermediary between the people (who are terrestrial beings) and the ancestors (who are celestial beings). Bediako Kwame, in his paper, succinctly described this role of an African ruler this way, ‘an African ruler is not to his people merely a person who can enforce his will on them. He is the axis of their political relations, the symbol of their unity and exclusiveness and the embodiment of their essential values. He is more than a secular ruler. His credentials are mystical and are derived from antiquity’ (Bediako, 2004: p.101). This ‘mystical credential’ of the African ruler is related to the traditional belief that the well-being of the society depends upon maintaining good relations with the ancestors on whom the living depends for help and protection. The ruler fulfils an important function as intermediary and is therefore the central figure ensuring the maintenance of the desired harmony between the living, that is his community, and the ancestors (Bediako, 2004; Mbiti, 1969).

Therefore, to show the community leaders respect is to respect the whole community and their beliefs. The relationship between the community leadership and the people reflects the beliefs of the African society with its brotherliness and ‘extended’ family concept. Every member of the community sees himself or herself as belonging to a larger family with the ruler as the father. As the father of the community he is highly respected.

‘as long as I am staying within the oba’s (king) community, there is nothing I can do because he has given the order, so it is like a parent over a community, whatever he says should be respected’ Molar

This approach of contacting first the community leadership as the starting point for community engagement was corroborated by Nyika *et al* in a review of case examples from

across Africa (involving Burkina Faso, Mali, Gabon and Tanzania) while engaging diverse communities participating in clinical trials noted that ‘in preparation for the clinical trials, several meetings with the communities were scheduled. The initial meetings were exclusively between the senior investigators and village chief with his elders. At these initial meetings, information about objectives, methodology, potential risks/benefits and importance of anticipated findings of the intended clinical trials was provided’ (Nyika et al., 2010, p.3). Establishing contact with the community leaders is also seen by the community as the proper and acceptable method of communicating with the whole community on issues of great importance like research and health services provision. This phase of community approach, also referred to as community entry by some authors (Angwenyi et al., 2014; Marsh, Kamuya, Mlamba, Williams, & Molyneux, 2010; G Okello et al., 2013), is therefore very important and must be well planned and executed by every researcher.

I argue that the dynamics of community approach by a researcher is consistent with the social capital theory⁸⁵. The researcher uses the bonding between the community leaders and members as an avenue for community entry. The utilization of the key role of the existing community authority structure therefore makes the community approach the key to success of community-engaged research and provides possible benefits of research that will contribute to community development. For example, Tindana and colleagues in their Ghanaian study showed that specific pre-existing features of the community greatly facilitated community engagement

⁸⁵ Social capital theory refers to resources inherent in social relations and networks that facilitate collective action. These networks include links, shared values and understandings that enable individuals and groups within a community to trust one another and work together towards a common good. I discussed social capital in section 9.2.3 p. 224-226.

and the use of traditional engagement mechanisms limits the social disruption associated with research conducted by outsiders (Tindana et al., 2011).

11.3.1.1 Community gatekeeping

The concept of community gatekeeping is an integral part of community approach. Some of the biomedical researchers with previous experience pointed out that the gatekeeping responsibility or role was not limited to the rulers or elders, although they were the central point of contact, but that the community health workers might play a special role in research like genomic research especially with the need to explain medical or genetic terminologies to the people, thus conferring on the health workers a unique educational responsibility.

‘And in any community, there are always leaders. There are also health workers too in that environment. These are influential people who can talk to the community members’

Dr Sharp

‘they will never agree with you, but it’s better to go through the community leaders or the clinic personnel or workers’ **Dr Matt**

The contribution of community health workers was first alluded to by these biomedical researchers in their responses. One of them gave an account of his experience on the research field and how it was difficult to recruit participants until the community health nurse in charge of the health care facility talked to the people. It was based on the opinions of these biomedical researchers that the community health workers, as potential playmakers and intermediaries in the community engagement process by serving as interpreters of medical terminologies and speaking the language the people understand, were recognized and included as study participants for my research. The biomedical researchers stressed that the health workers were acceptable to the people because they lived in the community, served as health educators to the people in the health

centers, understood the customs and norms of the community and were well positioned to gain the confidence and trust of the people if, and when they partnered with researchers in the research settings. One of the biomedical researchers said:

'You have to go through somebody the people know, going to them alone they will never agree with you, go through the health worker who will be able to explain what you want to do to them' **Dr Mouldy**

Leaders of social or professional groups within the community were also identified as 'subsidiary gatekeepers' like the market women group, male socio-professional clubs like the hunters, fishermen, farmers, and religious groups and so on. They were not replacing the community rulers and elders, but one of the biomedical researchers expressed their relevance in achieving community awareness of research. The leaders of these socio-professional groups play unique roles by engaging group members in effective communication, thereby giving them sense of belonging, and encouraging the community to make the research their own. In traditional Nigerian setting, which is like most sub-Saharan African settings, there is usually a women's leader called 'Iyalode' who serves as the leader of the market women. To create community awareness of research, the women in the community may be reached through the 'Iyalode' after the community ruler and elders have permitted the researcher to do so. It was suggested that these groups of leaders can serve as gatekeepers to reach potential research participants in the community, as illustrated by the response of this researcher,

'go through people who can reach them, the traditional heads, market leaders, and leaders of farmers, hunters,' **Dr Stephanie,**

and one of the adult males,

‘Community can be seen as various units, there are other influencing units outside the oba and the chiefs, we have the churches, schools, hospitals. Approach the heads of the units and inform them of what you want to do. You need to get consent from these people for them (the potential research participants) to agree’ Taylor.

11.3.1.2 Trust

Another key issue that evolved during the community approach stage is trust. It has been stated that ‘trust is everything’ in effective engagement of people (Pondrom, 2013), and it is the foundation for success of genomic research and governance of biobanking (Haldeman et al., 2014; Marsh et al., 2008; Marsh et al., 2011; Mongoven & Solomon, 2012). The building of trust in the genomic research process commences from the point the researcher contacts the community. The community members expected their leaders to scrutinize the researchers, that is confirm who the researchers are, where they are from, and ascertain that they are who they claimed to be, as stated by one of the adult males,

‘community elders are to scrutinize the research team, and make sure it is not found wanton’ Philemon.

This responsibility is akin to the community leadership serving as a ‘local or community ethics committee’ with the overriding goal of protecting potential research participants from harms and exploitation by ascertaining the integrity of any researcher entering the community. This is considered as part of the gatekeeper’s roles. The confirmation of the identity of the researcher serves to build trust between the community leaders and the researcher. Most of the focus group discussants emphasized the identification of researchers as a key factor that would enhance their participation in genomic research. Here are some of their responses:

'it is okay if the researcher's identity is confirmed, but if you cannot confirm who the researchers are then we have to refuse' Mary

'Collect the phone number, id card (of the researcher). Check their (researchers) documents, contact the elders who will check these documents' Flora

The concept of trust is linked to the fact that researchers are strangers to the community. The 'strangeness' is not only in terms of someone who is from outside the community but also denotes unfamiliarity with the communal norms and values. Therefore, the researcher approaches the community with the goal of getting to know the community and be known by them, then the researcher becomes familiar with the norms and practices of the community and assumes the status of an 'insider'. In this context, both the community members and biomedical researchers agreed that the community would respond positively to genomic research if they were engaged by an individual or people known to the community. This explained why the people trust their community representatives, the community health workers, community rulers and elders, because these are the people they know. This was supported by these excerpts from the data analysis:

'People that you know that they trust, they see as part of them that are not likely to deceive them, not likely to mislead them. So, you need people that they can believe, that is the traditional rulers, the religious leaders, school teachers, health teachers in communities' Dr Meadows

'As a total stranger, we will not give our consent, you will need to get someone we know and can trust like our sons, an in-law, someone that we are used to' Charlotte

‘Now I mean, whoever is the health worker that you’re going with, they will know they are people from the hospital, that’s how to move around. Hope you understand, they will readily accept to that.’ Franscine

Therefore, the impact of gatekeeping on community engagement is centered on trust. The people trusted their leaders to safeguard them and entrust their well-being into the hands of the community leadership, thus they expected the community leaders to scrutinize researchers, who in turn must earn the trust of the leaders. The people expected researchers to be truthful and keep to their promises. This conforms to the principle of veracity, one of the core principles of principlism (Azétsop & Rennie, 2010; Beauchamp & Childress, 2012; D Callahan, 2003b; Hursthouse, 1999). It also demands demonstration of virtue of fairness, respect and transparency on the part of the researcher (Gauthier, 2000; Holland, 2011). These principles extend to the relationship between the leadership and the people as well. That is, the community members also expect truth-telling and honesty from their own representatives.

The community approach stage is an opportunity for researchers to develop a cordial relationship with the community leadership and members. Most of the focus group participants opined that when researchers engage in local community activities like participating in their religious programs or social events, this creates a friendly bond that makes community awareness and participation of research less problematic. One of the biomedical researchers agreed to this view expressed by the focus group participants;

‘Forging a relationship with the community ‘most of the time there tends to be a disconnect between we, the researchers, and the larger community, we need to mingle and really be part of them’ Dr Sharp

However, I believed this view is more applicable to the locally based researchers who reside within and around the community as the respondents referred to researchers working in the research institution situated in the community. This may be related to seeing researchers as strangers if the researchers who reside within the community do not associate with community members. Then the potential research participants see them as ‘outsiders’ and demand for verification of their identities before they can be trusted. This was better expressed by one of the biomedical researchers;

‘if one has not been really interacting with the group of people, it may be difficult’ to get them to agree to participate in research. we should associate with them, and participate in community activities, not just when we have a need’ Dr Misty

It may be argued that close affiliation with one’s community may result in undue influence in research participation and recruitment. The community may interpret their participation in research as a way of pleasing or paying back researchers for past or present favours, like health-related benefits received from a researcher in the past. The community leaders and individuals may be unduly influenced and not consider the possible risks that may accrue from the research before giving their approval. In the context of African communalism where brotherhood and reciprocity are socially acceptable values, this is not seen as unethical by the community but based on western research ethics this constitutes conflict of interests, and therefore it is the responsibility of a locally based researcher to resolve this dilemma by either situating the research in another community or another investigator who is not affiliated to the community serve as the lead researcher and interact with the community leadership.

Once the initial phase of community approach is completed, then the researcher can ‘enter the community’. This means the community approach may be likened to ‘being met and greeted

at the door' by the community gatekeepers who, after being convinced of the researcher's motives and goals, approve of the research and permit community entry. The approval is akin to 'opening of the door to a visitor' (that is the researcher). Two of the community leaders opined that approval makes participation and recruitment of community members easier.

'people are not likely to agree but if we the leaders talk to them first it will not be difficult' **King Brown**

and

'You know it will be difficult for them (community members) but if you go through us (the community leaders), then we are the first to speak with them, it will not be difficult'
Elder Jonah

Though most of the respondents indicated that approval of research by the community leaders was crucial to its implementation this does not constitute informed consent, a view held by most of the biomedical researchers. However, this view was only held by a minority of the community respondents, and they felt that this approval was not synonymous with informed consent rather it signified that the researcher has been accepted to interact with the members of the community having received clearance as a trustworthy and virtuous person.

After the researcher has approached, presented himself and his intentions to, and gained the trust of, the community leadership then he would be able to interact with the community. It is at this stage he would be granted 'entry to the community' to pursue his goals. This phase of community entry which I termed the interphase is discussed next.

11.3.2 Community Interphase

The stage of community entry or interphase, when the researcher has gained the trust of and sustained the interaction with the community leaders, is the phase that precedes the ‘town hall meeting’ where contact is made with community members. It is characterized by deeper interaction with community representatives, initial integration of the communal norms and cultural beliefs into the research scheme, clarification of possible queries or potential conflicts, and preparation for effective communication of research to the people. During this stage, trust is sustained by disclosure of what research is all about, and genuine consideration of the cultural beliefs of the people and how these can be integrated into the research to prevent or minimize conflicts as much as possible.

11.3.2.1 Fostering partnership

During the community interphase stage, further deliberation with the community leaders promotes and strengthens trust. This is related to full disclosure of what the research entails, including disclosure of possible risks and benefits. One of the community elders put it this way,

‘we talk more about what you plan to do, then we are convinced that you are coming for a research, not something else’ Elder Jumbo

This implies that the community must have confidence in the scientist or researcher that their biological samples will not be used for any other purpose apart from that which the researcher has disclosed. Furthermore, the community members are reassured through their representatives that the motive of the researcher is not to cause harm but to seek ways of improving their health and contribute to knowledge.

‘We let them know this is what they (the researchers) are trying to do not to hurt or to harm so they (the community members) will be convinced’ Elder Johnson

The trust is gained and strengthened as the community engagement process progresses based on principle of veracity on the side of the researcher. As earlier stated, veracity demands truthfulness, openness and transparency. It is important for researchers to disclose details of research to forestall any possible conflict and distrust of science among the public. Public distrust has done great damage to scientific research in the past and present. The Tuskegee syphilis study⁸⁶ among the African Americans in the 1930s exemplified this (Affairs, 2016; Bhutta, 2004; Schulz, Caldwell, & Foster, 2003).

The ethical theory of virtue also applies here. A virtuous researcher will always seek to do the right thing, not to cause research participants harms even in the face of doing the greater good. The need to protect individuals and communities overrides the utilitarian goal of the research. Furthermore, in research, good character of the researcher aimed at protecting research participants is more important than conformity to a set of rules, so ‘instead of appealing to international conventions or government regulations to protect participants, the most reliable protection is a researcher with a character marked by informed conscientiousness, responsible sensibility and compassion’ (Hospice Friendly Hospitals, 2013, p.46).

11.3.3 Community Collaboration or Integration

The actual integration and participation of the community in the research project usually involves effective bi-directional discourse or communication between researcher and the potential research participants, the integration of cultural knowledge of the community, and building trust for a true partnership. In the context of the community-researcher interaction, social capital theory⁸⁷ which is about interactions and relationships fostering trust, cooperation and

⁸⁶ Details in section 3.2.1, p. 25

⁸⁷ I discussed social capital theory in section 9.2.3, pp. 224-226.

reciprocity is applicable. As a cordial relationship develops between the researcher and the community, the researcher gradually gets integrated into the community, in other words, gets 'bonded and linked' to the people. Based on this newly formed relationship, the researcher begins to share in the community's beliefs and cultural norms, and the community no longer sees them as a stranger because of the trust they have in them. The radius of trust between the community and the researcher becomes shorter. The radius of trust refers to the mechanism that facilitates cooperation among individuals, the circle of people among whom cooperative norms are operative. This infers that the closer a researcher gets to the people, not just in physical terms of distance but in the context of social integration, the shorter the radius of social interaction, and the higher the likelihood of gaining the trust of the community. The researcher must be in the radius of trust to effectively engage the community otherwise they remain an 'outsider' and the research flops.

This cultural integration of research reduces the risk of conflict and enhances acceptability of research among members of the community. High integration and high linkage interact one to another to produce social opportunities and resources (Woolcock & Narayan, 2000). Integration is a process that develops intra-community ties, the more intensive the social ties and generalized trust within a community are, the higher is the endowment of this form of social capital. Linkage is extra-community networks that is the bridges that can be built between two or more different communities (O'Doherty et al., 2011; O'Doherty, Hawkins, & Burgess, 2012). So, in the context of genomic research, the researcher, coming from a scientific research community, develops a tie with the research participants' community by building bridges that links up with the community leadership and members upon the foundations of trust and veracity.

Therefore, community engagement and its benefits are not possible if researchers do not take steps to understand the community they are engaging with. Engagement is based on community collaboration, and meaningful community participation in research extends beyond physical involvement to include generation of ideas, contributions to decision-making, and sharing of responsibility. Community participation in promoting and sustaining health was championed in the Declaration of Alma Ata on Primary Health Care, which stated that people have the right and duty to participate individually and collectively in the planning and implementation of their health care (World Health Organization, 1978). For example, in Kenya, community members have become increasingly involved in health research as volunteers and contracted employees referred to as village reporters. This involvement of community intermediaries between lay people and researchers emphasizes the importance of community engagement (Chantler et al., 2013). Their work emphasizes the need to understand the social context of research.

The Focus Group discussants, just like majority of the biomedical researchers, agreed that integrating the cultural norms of the community aids recruitment for and participation in research. The integration of cultural beliefs of the community to how research is implemented demonstrates respect for the community and recognition of privacy and communal autonomy. This can be illustrated with excerpts from responses of the FG participants and biomedical researchers:

'get to know their culture, what they believe in, you need to merge their belief with what you want to do' **Elizabeth.**

This view sums up the rationale for community-engaged research from the perspective of the research participants, incorporating cultural beliefs into research to aid community acceptance.

'get familiar with the beliefs of the people with regards to body parts and samples'

Dr Stephanie

'a researcher should actually become familiar with the beliefs and customs of the society where he or she hopes to carry out research, and then try to address some of these beliefs and taboos, for example voodoo, people using body samples and parts for spiritual (ritual) reasons, which I think are common things in this our environment' **Dr Mole**

Cultural integration may be enhanced by the role of the lay member on institutional ethics committee. One of the biomedical researchers pointed out that the presence of the community lay member on the institutional ethics committee may guide researchers in integrating cultural beliefs into the research design before the interaction of the researcher with the community because

'in the ethics committee, we have a member who is a representative of the community. The community representative will really help us a lot with all these superstitious beliefs and so on. He will be able to enlighten us better'. **Dr Shaw**

With such input from the lay member, the researcher will know what to envisage when he

'comes to the field after the proposal has been given approval by the ethics committee'

Dr Sharp.

It is at this stage that the researcher can be said to have obtained the community approval and can approach community members for individuals' consents to participate in genomic research and receive collaboration or partnership for the project in a reciprocal manner.

11.3.3.1 'Communicate in a language they understand'

The support of the community members is based on effective communication of research and appreciation of who the researchers are and attestation to their integrity. The effectiveness of

communicating research details to the community members depends largely on speaking the language the people understand, and this is not so much in the dialect or native language alone but also the techniques or strategies of communication, using body language and ‘slogans’ the people prefer and appreciate. It also involves presentation of benefits of the research in such a way that will appeal to the community, while at the same time reassuring them of the fact that risks, if there are, will be minimal and bearable.

There is an understanding that the community leaders and the health workers are in a more suitable position to do this. They approach the community in the company of the researcher to pass information to the people and achieve their collaboration. This can be done by calling the people together for a ‘town hall’ meeting or ‘community clinic assembly’ where the community representatives, the community health workers, and the researcher inform the people of the research and members of the community can clarify any issue that is ambiguous. This process encourages the people to make the research their own as effective communication aids building of trust between the researcher and the community.

*talk to the elders, then address a ‘town hall meeting’, ensure to speak in a language they understand so you may need to use an interpreter, and the people have opportunity to interact with you (the researcher)’ **Dr Stone.***

*‘After you have done that (after the community approach), there is need for you to address the community at a meeting. So, if the researcher does not know how to speak the local language, you will have to work with a colleague who can speak and understand the language very well. When you speak to them in a language that they understand, they are ready to give you their consent **Dr Soul.***

A community opinion leader is

‘a representative of that environment here at the community health center here, as one of our ward development community members. He will be able to speak to them in the language they best understand’ (Felicitas)

According to the biomedical researchers, this communication is a two-way dialogue. It is not just a unidirectional process whereby the researcher informs the people of what he wants to do and expects them to comply but gets a feedback from the community, allays their fears and gives them time to ponder on the information they have received before consenting to participate. Therefore, the researcher advances their quest for knowledge and the community benefits from the research by getting solutions to their health challenges.

‘It will not be a one-way thing whereby the researcher only sees it as an avenue to advance his own academic or research knowledge, but the community also sees it as one of the ways of solving their numerous health challenges’ Dr Sandy.

From my viewpoint, the effective communication of research to the people ‘in a language they understand’ demonstrates the ethical principle of respect of persons. This allows for a form of dialogic democracy, a concept that promotes voluntariness through individual conviction and decision to participate in research without coercion (Pohlhaus & Cook-Deegan, 2008; Secko et al., 2009). Individuals would know what is expected of them and choose to accept any possible risks for either altruistic reason or otherwise, while also enjoy the benefits that accrue from the research.

Also, the theory of citizen participation is applicable to the process of bi-directional exchange of information on genomic research with the community. This theory is a process

which provides individuals an opportunity to influence decisions on issues that affect their well-being. This theory has been for a long time a component of the democratic decision-making process (O'Doherty et al., 2011, 2012). Engaging the community in genomic research therefore is a means of ensuring that community members have a direct voice in health-related decisions. This implies that community members must be involved at the conception of research that involves them to contribute their views and opinions during the planning stage to the decisions taken on the implementation of such research. This is a type of interactive planning, different from traditional conventional planning that tends to be analytical and the planner is detached from stakeholders. Even if the researcher has completed a research protocol before coming to the field, which is often the case, the protocol may be modified during the community engagement process to allow for community integration in an ethical manner.

Interactive planning is an integrated approach that is appropriate and provides for interaction with the stakeholders in genomic research especially at the community level for relevant information dissemination, sharing of values, reaching of consensus, and ultimately proposing actions that are both feasible and acceptable. Interactive planning assumes that open, participative processes lead to better decisions, so the researcher engages directly with the community to gain support, build consensus, identify possible areas of ethical conflicts before the research, identify acceptable solutions, and secure implementation. According to Lane (2005), success in interactive planning, during the engagement process, is measured by the extent to which balance can be achieved among conflicting issues and consensus is reached on appropriate actions for research implementation (Lane, 2005).

To achieve effective communication in practical terms, that is ensuring that the right information is passed across to the people and the information is comprehensible and effective,

may necessitate getting an interpreter who can relay information to the people in their native language. Regarding genomic research which is my focus, this will require the assistance of health workers who are skilled in public enlightenment methods, who are also equipped to convey health issues to the people in native dialects using phrases, slogans, folklores and stories.

There is consensus among the researchers and the community members on the fact that benefits of research, and compensation for participants should be discussed during the community engagement process to aid research participation. Excerpts from the responses of biomedical researchers, FG participants and community health workers illustrate this theme:

‘to address them through public enlightenment and talking to the community leaders, involving key community members, opinion leaders and traditional rulers, explaining the benefits of research’ **Dr Mole**

‘community will allow, it depends on communication, people must be enlightened of the benefits, risks, and cost. There must be communication between the community and the researcher’ **Barnaby**

‘the people want to be convinced, they desire evidence that what you are about to do will benefit them’ **Franscine**

Regarding communication of benefits and compensation, one of the biomedical researchers suggested that researchers should engage in ‘social marketing’ when she said,

‘The best way to get the people is through their leaders, this also helps to ensure openness and transparency, and also engage in social marketing. The place of incentives must be discussed as one engages the community’ **Dr Sandy.**

By this, she suggested the application of the social marketing theory. This is a theory of mass communication that promotes socially valuable information and accepted behaviours, and therefore can be used to enhance the communication of a focus of interest and its benefits to the society. In the context of genomic research, she advocated for ‘selling the idea or concept of genomics’ (the socially valuable information) to the people in a manner that would appeal to them by emphasizing its health benefits to the society, not just individuals. She implied that researchers should emphasize the ‘social good’, the primary aim of social marketing, as they approached and disclosed the purpose of genomic research to the community leaders. Basically, social marketing seeks to influence behaviours that benefit individuals and communities for the greater social good.

This CE stage is characterized by use of existing community information system to disseminate details of the research to the community. The use of the local information dissemination system is considered by the community as the authentic way of letting the people know that the community rulers and elders have given their approval to conduct of research in the community.

‘the town crier announced to the town people, that is a genuine research, announced in the church, some uses the health centre, then it is genuine, then I will not mind participating’ Flora

I argue that community participation in genomic research requires:

- Sustained deliberation with the community through community health workers who are knowledgeable on health-related matters especially genetic and genomics, and skilled in health education strategies to assist in passing information on genomic research across to

the community members in their dialects using familiar illustrations that the people can understand. This achieves two objectives, namely: a). the community members understand what genomic research is and appreciate what is expected of them during the research process, and b). fosters trust since the information is passed across by health workers who they are familiar with, and the perceived interaction between the researcher and the health workers bridges the researcher to the community as illustrated by the social capital theory⁸⁸.

- Power sharing which encourages a sense of joint ownership of the research, which in turn facilitates participation and recruitment. This is based on the principle of fairness and competence, where fairness means that participants know what they are entitled to, they can be present when decisions are made about their involvement in the research and are at liberty to make their contributions, challenge, answer or argue about issues. Competence in this context refers to access to information and using the best available procedures for knowledge selection where knowledge may include scientific facts, norms or subjective claims. Power sharing therefore exists within the framework of consensus, thus the community is more meaningfully engaged and interested in the outcome of the research, and disputes are easily resolved through agreement if they occur.

11.3.4 Post-research cordiality

Post-research cordiality is the last stage in my community engagement framework. This stage is often overlooked. It comprises of the conclusive phase of research and prepares the research field for further and subsequent research projects. In a review of the existing literature on community engagement strategies for genomic studies in Africa by Tindana *et al* (2015), they

⁸⁸ This has been previously discussed in section 9.2.3, pp. 224-226.

concluded that though there were several community engagement strategies, most of them could only support early stages of the research project such as recruitment or research participants. They recommended further research to identify effective strategies that will engage participants and communities beyond the recruitment stage (Tindana et al., 2015), emphasizing the importance of engagement processes that transcends the research to include post-research stages.

It is important that the researcher does not ‘spoil the field’ after the completion of their research. The lack of veracity or trust between the researcher and the community makes it difficult, if not impossible, to get the community to participate in research in the future. In addition, the community members expect the researcher or the research team to sustain a cordial relationship with them.

‘And if there’s any testimony you have in the past that you have done before or somebody have done before that have led to the cure or preventing such illness because of that research, you will tell them. Those kinds of things will encourage them to open their minds’ Felicitas

‘So many people have come to take blood samples in the time past I never got my result’ Andrew

‘Trust has been betrayed that is why people do not respond.’ Janice

Once a relationship has been initiated during the process of community engagement, the community sees this as a lasting one, looking forward to further fruitful interaction with the team especially if the research is health-related. Local researchers are expected to show more intimate interest in community matters, serve as a link between them and the scientific world, and provide services that will benefit the community. Most of the biomedical researchers said that sustaining

cordial relationship with the community after the research has additional benefits for future consenting for further research and feedback of results. This observation was previously reported by Kamuya *et al* and Yarborough *et al* (Kamuya, 2013; Yarborough *et al.*, 2013).

‘Researches require quite a lot of integrity and trust. So, the members of the community demand for it. Having that time to attend to their health needs will give opportunity to build relationship with the members of the community; a lasting, mutual, trustworthy relationship with the people.’ Dr Shade

‘We should actually organize more educative sessions like in the mosques, in the churches, in different gatherings so that people are well informed about different health matters. They would have known that research is necessary even before we get to talk to them. We would have made the community know about research long before the research starts proper and should continue to do this even after the research is completed’ Dr Munchy.

11.4 Conclusion

In this chapter, I discussed how the dynamic process of community connections or networks was employed for community engagement in genomic research by a researcher based on community approach, community interphase, community integration and collaboration, and post-research cordiality. In the next chapter, I present the concluding part of my thesis comprising policy, social, academic or educational, and ethical implications of my research findings, and recommendations including a proposal of a model for community engagement process in genomic research based on my data.

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PART IV

CONCLUSION

CHAPTER 12

Conclusions, Implications and Recommendations

12.1 Synopsis of findings

Using qualitative approach based on a form of grounded theory and the constant comparative method for analysis, I approached my research questions by exploring the views and opinions of potential research participants, community leaders and community health workers located in a semi-urban community, and biomedical researchers in a research institution situated within the same community, on informed consent process and community engagement in genomic research. I enriched my analysis by building theories and arriving at normative conclusions using the symbiotic empirical ethics approach.

Firstly, my research findings demonstrated genomic illiteracy among majority of potential research participants and eight biomedical researchers, and genomic science literacy among 14 biomedical researchers and a minority of the potential research participants. Eight biomedical researchers, but no potential research participant, showed genomic health literacy. Secondly, I identified the factors that influenced the potential research participants to agree to participate in genomic research, and the effects of gender inequality and patriarchy on decision-making among study participants. The reasons for agreeing to participate included: trust in the researcher and their affiliated institution, understanding what the research is about, benefits of research, effective community engagement through recognized community authority leadership, feedback of genomic test results, and on the part of the adult participants, commitment to communal values – altruism, while on the part of the youth participants, personal convictions. The youths demonstrated a generational shift from absolute solidarity typical of African communitarianism towards ‘relative solidarity’ to explicate why they would want to participate in genomic research.

The recognition of this phenomenon by genomic researchers will hopefully prevent ethical conflicts among potential research participants.

Thirdly, my research showed that although blanket consent appeared acceptable to most biomedical researchers and the adult participants, there was disagreement over consent type preference between some of the biomedical researchers, community leaders and health workers. The community leaders and health workers posited that the community would not accept blanket and/or broad consent types but would prefer re-consenting. The community leaders, in agreement with a few of the biomedical researchers, however opined that the community may accept blanket consenting if the leaders appeal to the community. Some of the biomedical researchers opted for third party oversight and delegated consent with responsibility of consent placed on the research ethics committee. These discordant views from my data constituted potential areas of ethical conflicts in conduct of genomic research. The importance attached to feedback of results of genomic tests by the potential research participants in the consenting process was not reflected in the responses of most of the biomedical researchers. This is a significant observation in that it may negatively affect genomic research participation of individuals and communities.

In addition, the views of the potential research participants on biobanking and how biomedical researchers perceived the response of research participants to storage and export of their bio-specimens lacked consensus, a potential source of ethical conflict. Although, the biomedical researchers and potential research participants agreed on the negative impact of superstitious beliefs and myths linked to blood and other bio-specimens on storage and genomic research participation, majority of the biomedical researchers opined that potential research participants would not agree to donate their blood or body fluids whereas the potential research participants agreed to donate if they could trust the researcher and research institution.

Finally, my research showed that the type of community engagement strategies that are needed to achieve successful implementation of genomic research is a dynamic process of community connections or networks employed by a researcher based on community approach, community interphase, community integration and collaboration, and post-research cordiality. This model made up of these four concepts (see figure 11, p.308), provides a framework for effectively engaging the community in the conduct of genomic research based on recognition of existing community leadership structure, effective communication of research, gaining the trust of the community, appreciation of their cultural norms and practices, and sustaining an enduring cordial bi-directional relationship with the community.

My findings also revealed a lack of preparedness of biomedical researchers for genomic research based on their low levels of genomic health literacy and ethical awareness of the national code of health research ethics.

12.2 Implications and Recommendations

12.2.1 Implications

The findings of my study have several implications for the successful implementation of genomic research in Nigeria and other developing sub-Saharan African countries. As my focus was on informed consent processes and community engagement in the conduct of this type research, I discuss the policy, educational, social and ethical implications of my findings on these issues. Also, I offer suggestions and made recommendations on strategic frameworks for the development of ethical guidelines for conduct of genomic research in Nigeria, hoping that this will serve as template for other sub-Saharan African countries.

12.2.1.1 Ethical and policy implications

For the successful implementation of genomic research in Nigeria and other sub-Saharan African countries, the formulation and development of a robust and acceptable ethical framework on informed consent processes and community engagement is important.

Community engagement: The recent ethics and governance framework for best practice in genomic research and biobanking in Africa by the H3Africa Working Group on Ethics acknowledged that community engagement must be an integral part of all genomic research and biobanking in Africa, emphasizing that researchers should take time to become acquainted with the community, its culture and other relevant dynamics that need to be taken into consideration in the design of context-specific research processes . However, the document failed to offer a feasible strategic framework for the implementation of the community engagement process in the African setting.

To achieve the goals of community engagement in genomic research in Africa, a strategic framework that incorporates the basic elements of what the indigenous communities consider to be important in the participatory process is needed. In genomic research, potential participants want researchers to approach their community leaders first and obtain approval before contacting community members. The potential participants have confidence in the gatekeeping role of the community leadership especially for research that involves the use of blood and body parts. In addition, researchers should not ignore the subsidiary community leadership structures that comprise leaders of professional and social groups within the society, and community health workers, who are potential gatekeepers as well. When and if appropriately incorporated into the community engagement process, the subsidiary leadership will aid the community awareness of research and recruitment of research participants. Specifically, the community health workers can

assist in the communication of genomic research details to the people in a language they understand.

Proposed Model for Community Engagement in Genomic Research: Based on the responses obtained from the community research participants and biomedical researchers, I categorized the themes obtained from my analysis into four areas or stages, namely Community approach, Interphase, Community integration and post-research Cordiality (CICC) and proposed a four-stage model as a way of achieving effective community participation in genomic research. I believe this four-stage model satisfies the CLEAR model of Pratchett *et al* (2009) in which he proposed that research participation is most effective where citizens

- Can do – that is have reasons and knowledge to participate
- Like to – that is have a sense of attachment that reinforces participation
- Enabled to – that is are provided with opportunity for participation
- Asked to – that is they are mobilized through public agencies and civic channels, and
- Responded to – that is they see evidence that their views have been considered (Pratchett, Durose, Lowndes, Stoker, & Wales, 2009).

The ‘Can do’ is addressed by the community interphase stage that emphasizes effective communication and promotes the knowledge of the research among the community. The ‘Like to’ is linked to community integration stage when the sustained deliberation and cultural beliefs encourages power sharing and community sense of belonging. This stage also encourages collaboration thus like the ‘Enabled to’. The ‘Asked to’ and the ‘Responded to’ are covered by the Community interphase, integration and post-research cordiality stages.

These four phases can be represented with Figure 11;

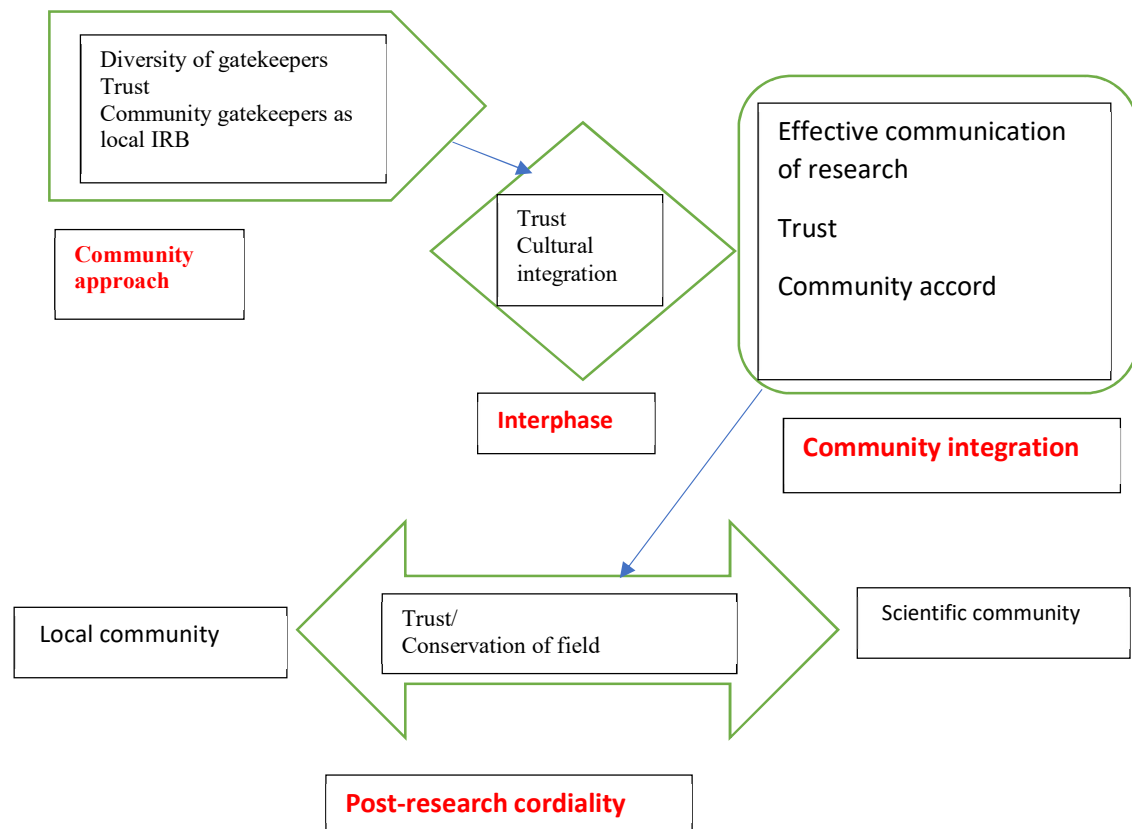


Figure 11 Proposed strategic framework for Community engagement in genomic research

Similarly, these four stages reflect the foundational features identified by Kolopack et al in their study (Kolopack et al., 2015)⁸⁹. More importantly, my model shows how community leadership and social structure are key features, while operational practices of discerning the community stakeholders, socializing the technology and research strategy, and establishing and maintaining a presence in the community reflect the stages of community approach, community integration, and post-research cordiality respectively. Brenner (2011), in his attempt to simplify frameworks for community engagement, identified three stages of community engagement which

⁸⁹The qualitative study by Kolopack et al is described in chapter three, section 3.3.3, p.57 under 'Models of community engagement'. They identified four foundational features of enabling conditions, leadership, core guiding values, and formative social science structure.

constitute a continuum. First stage is *community consultation* followed by *community participation or community based participatory research (CBPR)*, and lastly *community consent*.

I compared the stages of Brenner's model with my proposed model in Table 12.

Table 12: Comparison of Brenner's model and my proposed model of community engagement

| <i>Brenner's stages</i> | <i>Components</i> | <i>My proposed model</i> |
|---------------------------------|---|--|
| Community consultation | Formal dialogue or partnerships between researchers and the community regarding research designs and methods, may take place through focus group, town hall meetings or CABs | This is akin to community approach. The dialogue through focus group or town hall meetings occurs in the community collaboration stage in my model. |
| Community participation or CBPR | Equitable involvement, dialogue and exchange between researchers and community representatives in all aspects of the research process, encourages identification and establishment of the social relevance of the research and respect for the community's culture. | This is similar to the stages of interphase and community integration or collaboration. |
| Community consent | Solicit permission to conduct study through a formal consultation, agreements and participation | This is akin to community collaboration, although I prefer to use 'community approval' rather than 'community consent' as community consent does not in any way take away from the importance of the individual research participant's consent. It adds an element of security in traditional societies where communal consciousness and living is the norm. |

Brenner's model does not reflect some of the core principles of community engagement proposed by the CDC (2011)⁹⁰ which are present in my proposed model. The differences between my proposed model and Brenner's include: a) Brenner's model lacks clear distinction between community consultation and community participation; and b) the absence of post-research community engagement in Brenner's model. I demonstrate the similarity between my proposed model and the nine principles of community engagement by the CDC (2011) in Table 13.

The model I proposed in my thesis is a guide for researchers so that every important aspect of community engagement is covered when conducting genomic research. For example, community engagement should not be limited to before and during the conduct of genomic research but continues after the research – the phase of post-research cordiality. I recommend a document that itemizes the phases and the components of each phase as tick boxes to aid genomic researchers in the community engagement process. Also, I recommend that national health regulators and research ethics committees incorporate this four-phase approach in their ethical guidelines and requirements for conduct of genomic research and biobanking.

⁹⁰ Community engagement key function task force of the Centre for Diseases Control and Prevention, Atlanta proposed nine principles for Community Engagement. These include 1. Defining purposes, goals and population and 2. Knowing the community (these two principles apply before starting to work with a community); 3. Going to the community, 4. Looking for collective self-determination – that is helping communities to identify and name their health issues; 5. Community partnership, 6. Respect community diversity and culture, 7. Mobilise community assets and develop capacity, 8. Maintain flexibility – to adapt and change with community issues and needs for long-term collaboration, and 9. Commitment to collaboration – focusing on long-term partnerships to encourage potential for future successful outcomes (the last five principles are necessary for sustaining the success of the engagement process).

Table 13: Comparison of my proposed model with the Nine principles of Community Engagement by CDC

| <i>Stages</i> | <i>Principles of community engagement</i> | <i>Stages of my proposed model</i> |
|--|--|---|
| Before starting to work with community: | 1. Define purposes, goals and population 2. Know the community | Consistent with the stage of community approach |
| Items necessary for community engagement | 3. Go to the community 4. Look for collective self-determination | Consistent with Community approach stage |
| Success in community engagement process | 5. Community partnership 6. Respect community diversity and culture 7. Mobilize community assets and develop capacity 8. Maintain flexibility 9. Commitment to collaboration | Principles 5 – 7 are consistent with stages of interphase and community integration or collaboration. Principles 8 and 9 are consistent with post-research cordiality. |

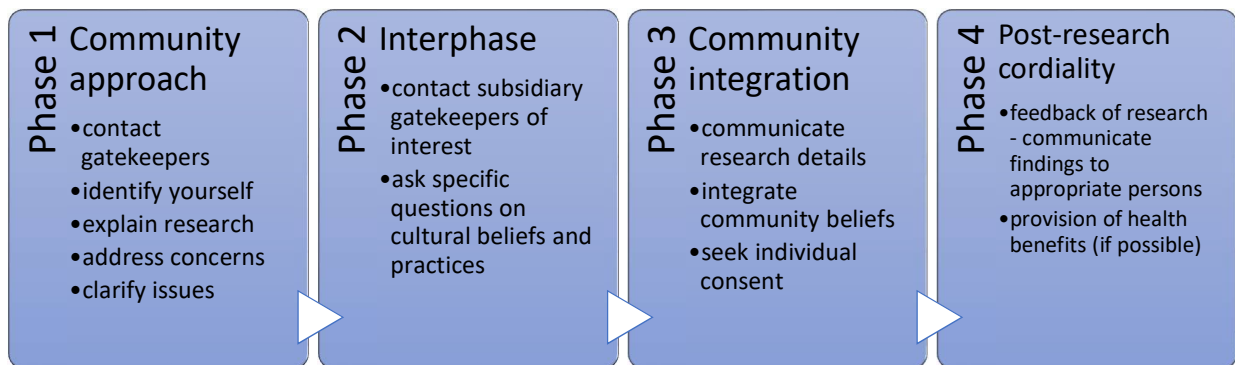


Figure 12: Proposed document for phased implementation of community engagement in genomic research

Researchers should address how they would engage participating communities at each phase in their protocols. By so doing, they would have given due consideration to the possible ethical issues they may encounter before contacting the community leaders. Thus, they are better prepared for the engagement process. The ethics committee may facilitate this by requiring it as part of the protocol submission process. I recommend that a post- research report on the impact of research on the community is required of researchers, debriefing and feedback from the community members be made compulsory as part of requirements for researchers when completing their projects to forestall distrust and strengthen the fourth phase of my model for community engagement in genomic research, that is post research cordiality,

Informed Consent: On choice of consent, a broad consent model has been suggested by the H3Africa Working Group. This may result in conflict considering that choice of consent may differ based on the preference of the participating community. The findings of my thesis suggest that various categories of participants within the same community may prefer different consent processes. Thus, researchers would need to exercise flexibility in the adoption of informed

consent choice for their projects. It is better to offer participants the option of making their choice after ensuring adequate understanding of research details. The consent process may be made to conform to what suits the potential research participants like getting the community leaders to assume third party oversight if the participants prefer specific consent, or delegated trustee.

The role of the community member on the ethics committees is important to the implementation of genomic research, especially in relation to the community integration and collaboration of research. Such community members are in a key position to scrutinize and offer advice on possible areas of conflicts between the research methods and the cultural beliefs and practices of the community. Although, it is already a standard practice to appoint community representative and religious leaders as members of ethics committees, their roles become more relevant when it comes to review of genomic research protocols. I also recommend that researchers include community representatives of professional or social groups as members of community advisory board to facilitate understanding of communal norms and practices, dissemination of information on research, recruitment of research participants, fostering trust and bonding with community members. Overall, to harmonise the governance of emerging biobanks in Nigeria and other sub-Saharan African countries, I recommend a robust, culturally sensitive, context specific, and socio-economically applicable ethical guideline that will address the fundamental ethical issues encountered in genomic research.

12.2.1.2 Educational implications

To achieve genomic research participation, there is need to fill the gap in genomic health literacy among the public and more importantly the biomedical researchers who will provide the information to potential research participants for the informed consent process. Sub-Saharan African countries, including Nigeria, engaging in genomic research should organize seminars

and/or training courses for scientists to educate and build capacity for competence in genomic literacy. For example, such educational campaigns will demystify the use of blood and body parts in research and, as the scientific community adapts medical diagnosis and treatment to genomics and personalized medicine, it may become imperative to incorporate training in genetics and genomics medicine in the undergraduate and postgraduate curricula of relevant disciplines in the higher education sectors to bridge the existing knowledge gap, hence preparing medical graduates for the challenges of genomic research and its medical applications.

Also, there is need to create awareness and improve the knowledge of the national code of health research ethics among biomedical researchers by incorporating modules on the national code in the curricula of seminars on ethics training, as this may translate into ethical conduct of genomic research and ensure protection of prospective research participants.

12.2.1.3 Social implications

The role of benefits, including financial inducements and compensations, in facilitating genomic research participation requires that researchers demonstrate virtue and transparency by ensuring they do not coerce and unduly induce potential research participants. Therefore, I recommend that researchers weigh the use of inducements against research participants' vulnerability by ensuring that incentives do not outweigh the intended demand put on the participants. In practical terms, appropriate incentives can be estimated by engaging with the community leadership or making a cost-benefit analysis based on information available from local researchers. In addition, potential research participants should be given time to adequately consider the possible risks of a research project before disclosing the intended benefits. I believe that educational campaigns, informal social interaction between the research team and

communities, as well as effective community engagement prior, during and after conduct of research will help to address the barriers of cultural and religious beliefs.

Local researchers and research institutions need to establish a cordial relationship with communities outside of research and eschew the mentality of the ‘unapproachable ivory tower’ to close the gap between the public and genomic science. This will facilitate healthy, cordial and productive interaction and trust which makes research implementation acceptable and easier. Cordial relationships between researchers and communities need not affect the validity of research. However, if such relationships create an ethical conflict of interest, then researchers must demonstrate virtue by not serving as principal investigators. Researchers without strong bonds or links can serve as principal investigators. It is also important to emphasize that researchers should not misplace community approval as general consent for potential research participants as this may create ethical conflict and confusion during and after research. Community leaders recognize the importance of individual consents, they also appreciate the fact that their approval of research positively influences the consent of the people although this is not invariable.

12.2.1.4 Research implications

My study identified the phenomenon of generational shift in consenting to participate in genomic research which has not been previously reported in the literature. This has implication for recruitment of research participants. Genomic researchers should involve various age groups in community engagement processes based on this generational shift concept. Also, I recommend the application of the concept of relative solidarity in resolving ethical conflicts encountered in the recruitment process among participants of genomic research by researchers or members of ethics committees. For example, while seeking participation for genomic research, different

approaches for recruitment may be advanced by researchers based on the understanding of the socio-cultural values and personal convictions of the potential research participants and communities. Sometimes these approaches may appear to conflict thus raising ethical concerns. For example, a researcher who chooses to approach younger people individually and older people through a communal meeting during recruitment for a genomic research may be seen as not engaging the community ethically. Therefore, in developing policy guidelines for review and approval of genomic research protocols, the model of relative solidarity could be usefully employed by ethics committees and other stakeholders to resolve the ethical issues raised by genomic research participation. I recommend further studies among other communities in Nigeria and in other sub-Saharan countries, using similar or different methodological approach, to corroborate this.

Further studies are also desirable on factors that facilitate or debar potential research participants in consenting to participate in genomic research from other sub-Saharan African countries. This is important in ensuring development of culturally relevant ethical guidelines for these communities. Similarly, further studies such as surveys are needed among biomedical researchers in other institutions and regions in Sub-Saharan Africa to identify knowledge gaps which can be addressed by funding agencies to prepare researchers for successful implementation of genomic projects.

12.3 Concluding remarks

This qualitative study explored the views and perceptions of potential research participants and biomedical researchers on informed consent process and community engagement in genomic research in a sub-Saharan African setting. On one hand, the findings showed that potential research participants would agree to participate and donate their bio-specimens for

genomic research if they trust the researcher, know the benefits and could receive feedback of results. However, they would not readily agree to storage or export of their biospecimens. On the other hand, there is poor genomic health literacy and low levels of awareness of ethical guideline for genomic research among the biomedical researchers, most of who preferred blanket consent. This study identified possible areas of ethical conflicts over differing preferences for consent types, discordant reasons for genomic research participation between adult and youth participants, disagreement between the biomedical researchers and community members on storage and export of bio-specimens, and emphasis on feedback of results as a condition for consenting to genomic research. Appropriate recommendations are suggested including a proposal for an effective strategic model for community engagement in genomic research in Nigeria and other sub-Saharan African settings. There is need for further research among potential research participants and biomedical researchers in other sub-Saharan African regions to explore how relative solidarity can be operationalized in approaches to consent, and to appraise the application of the proposed community engagement strategic framework in genomic research.

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APPENDICES

Appendix i

Ethics Approval – Local Institution in Nigeria

LAGOS UNIVERSITY TEACHING HOSPITAL HEALTH RESEARCH AND ETHICS COMMITTEE

PRIVATE MAIL BAG 12003, LAGOS, N
e-mail address: luthethics@yahoo.com

Chairman
ASSOC. PROF. N. U. OKUBADEJO
MB, ChB, FMCP

Administrative Secretary
MR. D. J. AKPAN
B.Sc. BUS, ADMIN, MIHSAN



Chief Medical Director:
PROF. AKIN. OSIBOGUN
MBBS (Lagos), MPH (Columbia), FMCPH FWACP

Chairman, Medical Advisory Committee
DR. M. O. OGUNLEWE
BDS, FWACS

LUTH HREC REGISTRATION NUMBER: NHREC: 19/12/2008a
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IGERIA address: luthethi3@yahoo.com

21st June. 2015

NOTICE OF **EXPEDITED** REVIEW App«pVAL

PROJECT TITLE: "COMMUNITY EWAGEMENT AND INFORMED CONSENT PROCESS IN RESEARCH —
REIEVANCE AND APPLICATION TO THE NIGERIAN NATIONAL CODE OF HEALTH RESEARCH ETHICS".

HEALTH RESEARCH COMMATTEE ASSIGNED ADM/ocsWHREC/1792

NAME OF PRINCIPAL PROF. OLOBUNMI OGUNRIN

ADDRESS OF PRINCIPAL INVESTIGATOR: UNITED KINGDOM.

DATE OF RECEIPT OF VALID APPLICATION: 28-05-15

This is to inform you that the research described in the submitted protocol, the consent forms, and all other related materials where relevant have been reviewed and given full approval by the Lagos University Teaching Hospital Health Research Ethics Committee (LUTHHREC).

This approval dates from 01-06-2015 to 01-06-2016. If there is delay in starting the research, please inform the HREC so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of this dates. All informed consent forms used in this study must carry the HREC assigned number and duration of HREC approval of the study. In multiyear research, endeavor to submit your annual report to the HREC early in order to obtain renewal of your approval and avoid disruption of your research.

The National code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the code including ensuring that all adverse events are reported promptly to the HREC. No changes are permitted in the research without prior approval by the HREC except in circumstances outlined in the code. The HREC reserves the right to conduct compliance visits to your research site without previous notification.

CHAIRMAN
PROF. N. U. OKUBADEJO

CHAIRMAN, LUTH HEALTH RESEARCH ETHICS COMMITTEE

Appendix ii

Ethics Approval – University of Liverpool

I am pleased to inform you that IPHS Research Ethics Committee has approved your application for ethical approval. Details and conditions of the approval can be found below.

Ref: IPHS-1415-LB-270-

PI / Supervisor: Lucy Frith

Title: Community engagement and informed consent process in genomic research – relevance and application to the Nigerian National Code of Health Research Ethics (Community engagement and consent process in genomic research)

First Reviewer: Judi Smith

Second Reviewer: Ian Schermbrucker

Date of Approval: 16th September 2015

The application was APPROVED subject to the following conditions:

Conditions

1. All serious adverse events must be reported to the Sub-Committee within 24 hours of their occurrence, via the Research Governance Officer (ethics@liv.ac.uk).
2. This approval applies for the duration of the research. If it is proposed to extend the duration of the study as specified in the application form, IPHS REC should be notified as follows. If it is proposed to make an amendment to the research, you should notify IPHS REC by following the Notice of Amendment procedure outlined at <http://www.liv.ac.uk/researchethics/amendment%20procedure%209-08.doc>.
3. If the named PI / Supervisor leaves the employment of the University during the course of this approval, the approval will lapse. Therefore please contact the Institute's Research Ethics Office at iphsrec@liverpool.ac.uk in order to notify them of a change in PI/Supervisor.

Best wishes

Liz Brignal
Secretary, IPHS Research Ethics Committee
Email: iphsrec@liv.ac.uk

Appendix iii

Interview topic guide

Demographic data of the study participants

This shall be obtained using a prepared format as presented below:

Age (years) Sex (Male/Female)

Domicile

Level of education (No education, Home tutor, Primary, Secondary, Tertiary)

Ethnicity (Yoruba, Igbo, Hausa, others)

Religion (Islam, Christianity, African Traditional, others)

Level of Income (average per year in Naira)

Area of research (for biomedical researchers)

Role in the community (for opinion leaders or community elders)

| S/N | Topic of interest | Question |
|-----|-------------------|----------|
|-----|-------------------|----------|

| | | |
|----|--|---|
| 1. | Process of decision making in the community | How does an individual make decision to participate in a venture/project/undertaking within the community? If the venture is a research, how will he/she decide to participate? Has there been any change in the decision making process? If yes, why and when? Is there any input to that decision from the community authority/family members/others? If yes, what type of input? Are there other factors that influence such decision? Which are these |
|----|--|---|

factors, and how they do influence your decision making ability?

2. **Knowledge of genomic research**

Have you ever heard of genomic research?

If yes, could you tell me what genomic research looks at?

If no, (this is what it is - genomic research looks at the human genome which is the complete makeup of the human DNA that predict chances of developing diseases in life or pattern of inheritance of diseases).

3. **Impact of cultural and religious beliefs on research participation**

Do you think that religion can affect participation of individuals in research? How does it affect participation?

Does your culture encourage participation in research? Are there cultural practices or norms that affect participation of community members in research? What are these practices? How do they affect research participation? Are there norms that allow or disallow different genders or age groups to participate in research?

4. **Knowledge of informed consent and who gives the consent**

Could you tell me what 'informed consent' (agreeing to participate in research or any other project after you have received full information on what the project is about) means? How much information will you need to agree to participate in genomic research? Can you give me some examples of such information? What do you think the process should entail? In genomic research, do you think informed consent is important? In genomic research,

specimens (e.g. blood samples) may be used for other purposes apart those initially given. This will be explained in the study information given to potential study participants. Do you think your consent for the initial purposes is sufficient to cover for the new purposes? If not, why? What will you want the researcher to do?

5. **Awareness of benefits and risks of research** Do you think research is associated with any risk? What of genomic research? What are these risks? Can you give examples of such risk associated with research within your community (if there is any)? Are there benefits associated with research? What of genomic research? Can you give examples of such benefits associated with research (if there is any)? How did you know about these risks and benefits?

6. **Appreciation of importance of ethics in research in the community** Ethics regulate research by reviewing research protocol, monitoring implementation and ensuring researchers do what is right. Do you think this is necessary? Can you tell me the reasons for your answer?

7. **Perception of export of donated specimens, ownership of such specimens and desirability for feedback following analysis of specimen** If you were asked, would you provide consent for your specimen collected for research purposes be taken somewhere else in Nigeria for analysis? If not, why? Would you provide consent for your specimen to be analyzed outside Nigeria? If not, why?

Who do you think own specimens collected for research? Why do you think so? Would you want to receive the

- results of the analysis on your specimen? How would you want to receive the results? Do you think your family members should be informed of the result if it may impact on their health? Why do you think so?
8. **Perception of community participation in research**
(I will explore how much trust the community has in researchers)
- What does the community expect from researchers who want to conduct research in the community? Are there rules or customary norms they need to comply with?
- Will the community want to be part of the conduct of a research? If not, why? If yes, which part of the research will the community want to have an input? How will you want researchers to go about involving the community in their research? Can you give me examples?
9. **Awareness and adequacy of the national code of health research ethics in conduct of genetic and genomic research (for biomedical researchers)**
- Are you aware of the National Code of Health Research Ethics? How did you know about it?
- Is there any guideline for conduct of genomic research in Nigeria? Do you think the Code, as it is presently, sufficiently covers the conduct of genomic research in Nigeria? Is there need for any guideline for genomic research? What are the ethical issues you will like a guideline on genomic research in Nigeria to address?

Thank you for choosing to participate and for your time.

Appendix iv

Discussion topic guide

Demographic data of the study participants to include gender, level of income, ethnic orientation, religious affiliation, age and level of education

This shall be obtained using a prepared format as presented below:

Age (years) Sex (Male/Female)

Domicile

Level of education (No education, Home tutor, Primary, Secondary, Tertiary)

Ethnicity (Yoruba, Igbo, Hausa, others)

Religion (Islam, Christianity, African Traditional, others)

Level of Income (average per year in Naira, if applicable)

Role in the family FGD Category

| S/N | Topic of interest | Question |
|-----|--|---|
| 1. | Knowledge of genomic research | Have you heard of 'research' before? Can you tell me what you understand by the word 'research'? Have you heard of genomic research before? What does genomic research mean? How did you know about it? |
| 2. | Importance of ethics in research in their communities | Do you know what ethics mean? Do you think ethics is important in research? What is the significance of ethics in research? Can you explain why it is important? |
| 3. | Process of decision making in the community | If you have to participate in research how will you make a decision? Has there been any change in the decision |

- making process? If yes, why and when? Is there any input to that decision from the community authority/family members/others? Are there other factors that influence your decision?
4. **Awareness of benefits and risks of research**

Do you think research is risky? What of genomic research? Can you tell me some of these risks? Can you give examples (if there is any)? Do you think there are benefits associated with research? What of genomic research? Can you give examples (if there is any)? How did you know about these benefits and risks?
 5. **Impact of cultural and religious beliefs on research participation**

Does your religion affect participation of individuals in research? How does it affect participation? Does your culture encourage participation in research? Are there cultural practices or norms that affect your participation in research? What are these practices? How do they affect your participation? Do you think your gender/age group put you at a disadvantage as regards research participation?
 6. **Knowledge of informed consent and who gives the consent**

What does 'informed consent' (agreeing to participate in research or any other project after you have received full information on what the project is about) mean to you? How much information will you need to give your consent for participation in genomic research? What do you think the process should entail? In genomic research, do you think informed consent is important? In genomic research,

specimens may be used for other purposes apart those initially given. Do you think your consent for the initial purposes is sufficient to cover for the new purposes? If not, why? What will you want the researcher to do?

7. **Perception of export of donated specimens, ownership of such specimens and desirability for feedback following analysis of specimen**

Will you allow your specimen collected for research purposes be taken somewhere else in Nigeria for analysis? Will you export outside Nigeria for analysis? If not, why? Who do you think own specimens collected for research? Why do you think so? Will you want results of the analysis on your specimen report back to you? How will you want to receive the results? Do you think family members should be informed of the result if it may impact on their health? Why do you think so?

8. **Perception of community participation in research**

What do you expect from researchers who want to conduct research in your community? Do you know of any customary norms they need to comply with? Will you want to have a say in which type of research is conducted in your community? Which part of the research will you want to have a say? How will you want researchers to go about involving you in their research?

Thank you for choosing to participate and for your time.

Appendix v



PARTICIPANT'S INFORMATION SHEET

Dear Participant,

Title of study

Community engagement and informed consent process in genomic research: application and relevance to the Nigerian Code of Health Research Ethics

Version number and date: Information sheet 01/May 4 2015

About this Study

You are being invited to participate in a research study on how to get individuals and communities to give their consent and take part in genomic research in Nigeria. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and feel free to ask us if you would like more information or if there is anything that you do not understand. Please also feel free to discuss this with any close relative if you choose to. We would like to emphasize that you do not have to accept this invitation and should only agree to take part if you want to. Thank you for reading this.

What is genomic research?

Genomic research involves the use of human biological specimens like blood, saliva, and other body fluids in the analysis of DNA to determine the why and how diseases are passed from one family member to another, and also seek possible treatments and ways of preventing these diseases from being passed onto other family members. This type of research often involves collection of body samples (like saliva, blood, urine, tissues, organs, etc.) from you and other members of your family or community members for analysis, export of these samples to laboratories outside Nigeria, the possibility your samples may be used for additional analysis other than what it was initially collected for and the result shared with other researchers.

Our study objective

This study is to find out what your view is about this type of research. We would like to know if you will agree to participate in such research and what you would take into consideration before you give your consent to participate. Also we would like to know how researchers/scientists can effectively get the members of the community to participate in this type of research.

Why am I chosen?

You have been chosen to take part in this study because you have been attending this hospital or facility which makes you a potential participant of this type of research. All patients and staff members of this facility/hospital are eligible to participate if they fit into our selection criteria. It is however important you know that your participation is entirely voluntary, and should you agree to participate you are free to withdraw from the study at any time without explanation and without incurring a disadvantage. Your withdrawal will not affect the service or care you have been receiving from this hospital.

What to expect

If you choose to participate, you will be expected to take part in an interview and/or group discussion. This will be arranged for a time that will be convenient for you in a comfortable place. If you are participating in the group discussion you will be in a company of other seven people. The discussion will last for a period of approximately 1 hour (but not more than 90minutes). I am the researcher and I will be moderating the discussion or conducting the interview. The discussion will be audio-taped.

We are mindful of the extra demand this may place on you especially the transport fares, so you will be given transport reimbursements, and refreshments during the discussion session. We do not envisage any risk, but if you perceive any discomfort or disadvantage by reason of your participation make this known to us. There are no direct benefit to you for participating but this study gives you the opportunity to air your views on this type of research.

All the information obtained from you will be kept confidential and all identifying personal details will be removed. The information will be used for this research only and stored in a secured hard drive on a protected computer.

The results of this study may be published in a scientific journal, the details of which will be made known to you. Strict anonymity will be maintained throughout the study and during process of communication of research findings.

In case of any complaint as a result of your participation in this study, please feel free to contact the following:

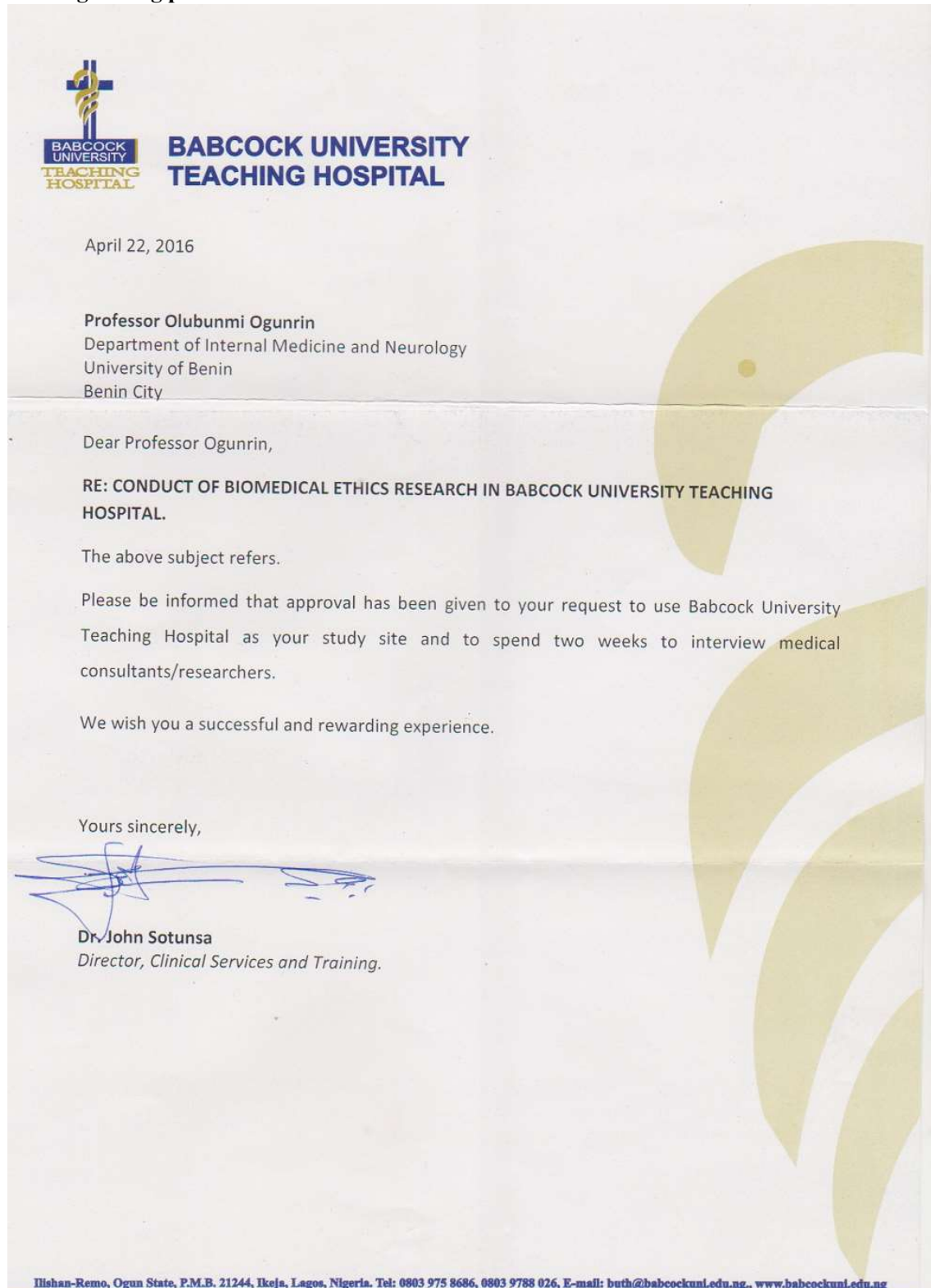
- a. Dr. Lucy Frith, Department of Health Services Research, Institute of Psychology, Health and Society, University of Liverpool, L69 3BX, United Kingdom, email: L.j.frith@liverpool.ac.uk
- b. Olubunmi Ogunrin, Department of Health Services Research, Institute of Psychology, Health and Society, University of Liverpool, L69 3BX, United Kingdom (+447448839773), email: olubunmi.ogunrin@liverpool.ac.uk OR Neurology Unit, Department of Medicine, University of Benin Teaching Hospital, PMB 1111, Benin City, Nigeria (+2348023344044) email: bunmi_ogunrin@ubth.org
- c. Research Governing Officer, University of Liverpool email: ethics@liv.ac.uk
- d. Professor Njideka Okubadejo, The Chair, Research Ethics Committee, Lagos University Teaching Hospital, Idi-Araba, Lagos Nigeria at njide_okubadejo@yahoo.com (mobile: 2348023130243)

Thank you.

(ADM/ocsWHREC/1792: 01-06-2015 – 01-06-2016)

Appendix vi

Letter granting permission for interview



Appendix vii



PARTICIPANT CONSENT FORM

Community engagement and informed consent process in genomic research: application and relevance to the Nigerian Code of Health Research Ethics

Names and Addresses of researchers

- e. **Dr. Lucy Frith**, Department of Health Services Research, Institute of Psychology, Health and Society, University of Liverpool, L69 3BX, United Kingdom, email: L.j.frith@liverpool.ac.uk
- f. **Prof. Mark Gabbay**, Department of Health Services Research, Institute of Psychology, Health and Society, University of Liverpool, L69 3BX, United Kingdom, email: mbg@liverpool.ac.uk
- g. **Dr. Kerry Woolfall**, Department of Health Services Research, Institute of Psychology, Health and Society, University of Liverpool, L69 3BX, United Kingdom, email: Woolfall@liverpool.ac.uk
- h. **Olubunmi Ogunrin**, Department of Health Services Research, Institute of Psychology, Health and Society, University of Liverpool, L69 3BX, United Kingdom (+447448839773), email: olubunmi.ogunrin@liverpool.ac.uk

Purpose of Study

This study is to find out what your view is about genomic research. We would like to know if you will agree to participate in such research and what you would take into consideration before you give your consent to participate. Also we would like to know how researchers/scientists can effectively get the members of the community to participate in this type of research.

Estimated number of participants

An estimate of 57 participants (until saturation)

What you will be expected to do

You will be expected to take part in an interview or group discussion. This will be arranged for a time that will be convenient for you and in a comfortable place. If you are participating in the group discussion you will be in a company of other seven people. The discussion will last for a period of approximately 1 hour (but not more than 90minutes). The discussion will be audio-taped.

If you are going to be interviewed, this will last for 60 to 90 minutes. The time for interview will be arranged taking your convenience into consideration.

Duration of study

This study will last a period of about six months to a year. The study will end as soon as the researcher has obtained the necessary information to answer the research questions.

Duration of participant's involvement

Each participant will spend between 60 and 90 minutes.

Cost to participant

Your participation will cost you your time (as stated above).

Risks

We do not envisage any risk, but if you perceive any discomfort or disadvantage by reason of your participation make this known to us.

Benefits

There are no direct benefits to you for participating but this study gives you the opportunity to air your views on this type of research and get a better understanding of what this type of research entails.

Compensation

We are mindful of the extra demand this may place on you especially the transport fares, so you will be given transport reimbursements, and refreshments during the discussion session.

Confidentiality

All the information obtained from you will be kept confidential and all identifying personal details will be removed. The information will be used for this research only and stored in a secured hard drive on a protected computer.

Voluntariness

It is important you know that your participation is entirely voluntary, and you are free to withdraw from the study at any time without explanation and without incurring a disadvantage. Your withdrawal will not affect the service or care you have been receiving from this facility/hospital.

What happens to the result of study?

The results of this study may be published in a scientific journal, the details of which will be made known to you. Strict anonymity will be maintained throughout the study and during process of communication of research findings.

Complaints from Study

In case of any complaint as a result of your participation in this study, please feel free to contact the following:

- i. Dr. Lucy Frith, Department of Health Services Research, Institute of Psychology, Health and Society, University of Liverpool, L69 3BX, United Kingdom, email: L.j.frith@liverpool.ac.uk

- j. Olubunmi Ogunrin, Department of Health Services Research, Institute of Psychology, Health and Society, University of Liverpool, L69 3BX, United Kingdom (+447448839773), email: olubunmi.ogunrin@liverpool.ac.uk OR Neurology Unit, Department of Medicine, University of Benin Teaching Hospital, PMB 1111, Benin City, Nigeria (+2348023344044) email: bunmi_ogunrin@ubth.org
- k. Research Governing Officer, University of Liverpool email: ethics@liv.ac.uk

Giving your Consent

Before participating in this study, it is important that you understand the purpose of this study, what you are expected to do as a participant, the risks (if any) and benefits (if any), the fact that your participation is voluntary and that you can withdraw anytime from the study without incurring any disadvantage.

First question: Do you have any questions on any issue related to this research?

Second question: Do you understand all the information you have been given on this research?

If your response is NO to the first question and YES to the second question, and you are willing to participate, then kindly give your consent below.

I (name), affirm that I understand what this research is about, what is expected of me as a participant, the risks and benefits, that my participation is voluntary and that I can withdraw any time without incurring any disadvantage, therefore I hereby give my consent to participate in this research.

.....

Signature (Participant)/Thumb-print

.....

Date

.....

Signature (Witness)

.....

Date

Appendix viii

Coding frame for analysis

| TOPIC AREA | CODE NUMBER | CODE | DESCRIPTION OF CODE |
|---|--------------------------------|--|---|
| DECISION MAKING | DM1 | Participants make decisions based on personal preferences and choices | The presence of individuals who make decision based on their personal choices, without consideration for other values |
| | DM2 | | Identification of other factors or values that affect individual decision making |
| | DM2-1 | Family influences affect decision making | |
| | DM2-2 | Consideration of communal preferences affect decision making | |
| | DM2-3 | Consideration of cultural and religious beliefs affect decision making of the individual | |
| DECISION MAKING IN RESEARCH SCENARIO | DM3 | The factors that influence decision to participate in research | Discussion to explore the impact of cultural and religious beliefs, and other factors on research participation |
| | DM3-1 | Consideration of family influences and choices | |
| | DM3-2 | Communal choices affect decision made by individual to participate | |
| | DM3-3 | Cultural/Religious influence on individuals' decisions | |
| | DM3-4 Financial empowerment | The role of financial empowerment in decision to participate in genomic research | This factor needs be explored as it emerged from respondents' comments |
| CHANGE IN DECISION MAKING PATTERN | DM4 | Identification and scrutinizing of views and comments that may possibly account for | Checking for identified factors among the respondents' groups |
| | DM4-1 Financial power | | |

| | | | |
|---------------------------------|---|---|---|
| | DM4-2 Individual independence DM4-3 Weighing personal risk against family and community risk DM4-4 Disparity in decision making among age groups | changes in the expected decision making pattern among the respondents | and deducing the significance of the differences in responses |
| GENOMIC RESEARCH | GEN1 GEN1-BR GEN1-RP GEN1-CL | Knowledge of genomic research Knowledge among biomedical researchers Knowledge among potential research participants Knowledge among community leaders | Information on the understanding of genomic research among the participants Mention human genome and analysis of DNA for predicting diseases |
| INFORMED CONSENT | IC1 IC1-BR IC1-RP IC-CL | Knowledge of informed consent Knowledge among biomedical researchers Knowledge among potential research participants Knowledge among community leaders | Information on the understanding of informed consent Mention disclosure of research details, voluntariness, comprehension and competence |
| INFORMED CONSENT PROCESS | IC2 IC2-1 Risk encountered during the conduct of research IC2-2 Benefits accrue from research | What information need to be provided to facilitate consent for genomic research | |

| | | | |
|---|--|--|--|
| | IC2-3 The procedures like donation of specimens, type of tests to be done, and where research will be conducted, etc. | | |
| TYPES OF CONSENT PROCESS | IC3 IC3-1 Preference and consensus for broad consent (in which case the respondent prefers to consent to all known and unknown tests) IC3-2 Preference and consensus for re-consenting, or tier consenting IC3-3 Reasons for lack of consensus | Information to explore the preference of potential research participants and community leaders for type of consent process | Distinguish between broad, blanket, re-consenting, dynamic consenting, third party/delegated trustee ⁹¹ |
| CONSENT FOR STORAGE AND EXPORT OF BIOLOGICAL SPECIMENS | SE1 Consensus for storage and export of biological specimens SE2 Lack of consensus for storage and export of biological specimens SE3 Indecisive SE4 Identification of reasons for disagreement in opinions | | |
| DESIRE FOR FEEDBACK OF RESEARCH RESULTS | FD1 Consensus for feedback of results FD2 | | |

⁹¹ Blanket consent is a process by which individuals donate their samples without any restriction. In re-consenting, participants are required to consent to the current study and then subsequently to each future research study involving the use of their samples. Broad or general consent refers to a process by which individuals donate their samples for a broad range of future studies, subject to specified restrictions. Consent is presumed when donors allow use of their samples and information for all research unless they actively choose to opt out. Dynamic consent involves the use of information technology to allow participants active involvement in the consent process. In third party or delegated trustee, participants transfer consent to a trustee or REC respectively.

| | |
|--|--|
| | <p>Lack of consensus for feedback of results</p> <p>FD3 Indecisive</p> <p>FD4 Explore preference for either personal or communal feedback</p> |
| EXPECTATION OF THE COMMUNITY FROM RESEARCHERS | <p>CE1 Discussion on what the community members expect from researchers before conducting research in the community</p> |
| WHEN AND WHICH PART OF THE RESEARCH THE COMMUNITY MEMBERS WILL WANT TO PARTICIPATE IN | <p>CE2 Opinions of respondents on at what stage of research should the community be engaged, and how to engage the community</p> <p>CE2-1 Views of the community</p> <p>CE2-2 Views of the biomedical researchers</p> <p>CE2-3 Is there any consensus?</p> |
| KNOWLEDGE OF THE NIGERIAN NATIONAL CODE OF HEALTH RESEARCH ETHICS | <p>NCHRE Knowledge of the national code among the biomedical researchers</p> <p>NCHRE1 Has knowledge of the Code</p> <p>NCHRE2 Lack knowledge of the Code</p> |
| ADEQUACY OF THE NIGERIAN CODE FOR CONDUCT OF GENOMIC RESEARCH | <p>NCHRE3 Explore if the code covers ethical conduct of genomic research</p> |
| | |

Appendix ix

Definition statement for genomic research

Genomic research looks at the human genome which is the complete makeup of the human DNA that predict chances of developing diseases in life or pattern of inheritance of diseases among populations. It involves scientists analysing the genome and looking for abnormal genes or DNAs that are responsible for causing diseases or abnormal reactions to drugs before they occur.

Appendix x



Community engagement and informed consent process in genomic research – relevance and application to the Nigerian National Code of Health Research Ethics

Debriefing Form for Participation in a Research Study

University of Liverpool

Thank you for your participation in our study! Your participation is greatly appreciated.

Purpose of the Study:

- a. We previously informed you that the purpose of the study was to find out how researchers can engage community, and how the interplay of culture and the practice of communality affect the process of informed consent, in conduct of genomic research in Nigeria. We specifically explored what your perception and interpretation of research is, and specifically genomic research,
- b. We asked you how you think the community ties or family ties affect decision making in genomic research,
- c. We also found out what the roles of community elders, opinion leaders, family heads and community members were in consenting to participation in genomic research and more specifically in storage, ownership, export and future uses of human body samples,
- d. And also explored the perception and understanding of biomedical researchers to community consultation and informed consent process in genomic research and specifically banking of bio-specimens, and we hoped to
- e. Propose guidelines for the implementation of ethical conduct of genomic research to the Nigerian National Health Research Ethics Committee for incorporation into the National Code of Health Research Ethics as soon as we conclude the analysis of the results.

So the questions we sought to answer when we asked for your participation included:

- a. How do potential research participants within the Nigerian communities perceive genomic research, i.e. what do they understand by research? What do they understand by genomic research?
- b. Is individual consent preferred to community consent in genomic research in Nigerian communities?
- c. How will Nigerian communities react to collection of bio-specimen for genetic analysis? Will communities or research participants agree to collection of their samples for analysis by unknown researchers in distant laboratories?
- d. How do cultural beliefs (as expressed by community 'gatekeepers' i.e. community elders, opinion leaders and family heads) interplay with community engagement in genomic research?
- e. Do biomedical researchers view community consultation and participation as a pre-requisite to successful conduct of genomic research in Nigerian communities?

We believed your responses had assisted us in answering these questions.

In case any of the questions asked may have provoked strong emotional reactions we do not provide mental health services and we will not be following up with you after the study. However, we want to provide every participant in this study with a comprehensive and accurate list of clinical resources that are available, should you decide you need assistance at any time. Please see information pertaining to local contacts at the end of this form.

Confidentiality:

You may decide that you do not want your data used in this research. If you would like your data removed from the study and permanently deleted please let us know either by phone or email. The contact details are provided at the end of this form.

Final Report:

If you would like to receive a copy of the final report of this study (or a summary of the findings) when it is completed, please feel free to contact us.

Useful Contact Information:

If you have any questions or concerns regarding this study, its purpose or procedures, or if you have a research-related problem, please feel free to contact the researcher(s),

- a. Olubunmi Ogunrin, Department of Health Services Research, Institute of Psychology, Health and Society, University of Liverpool, L69 3GL, United Kingdom (mobile phone: +447448839773, e-mail: olubunmi.ogunrin@liverpool.ac.uk OR Department of Medicine, University of Benin Teaching Hospital, PMB 1111, Benin City, Nigeria (mobile phone: 2348023344044, e-mail: bfunmi@uniben.edu)**
- b. Professor Njideka Okubadejo, The Chair, Research Ethics Committee, Lagos University Teaching Hospital, Idi-Araba, Lagos ((+2348023130243), e-mail: njide_okubadejo@yahoo.com**
- c. Dr. Lucy Frith, Department of Health Services Research, Institute of Psychology, Health and Society, University of Liverpool, L69 3GL, United Kingdom (email: L.j.frith@liverpool.ac.uk)**

If you have any questions concerning your rights as a research subject, you may contact the following:

Professor Njideka Okubadejo, The Chair, Research Ethics Committee, Lagos University Teaching Hospital, Idi-Araba, Lagos Nigeria at njide_okubadejo@yahoo.com

If you feel upset after having completed the study or find that some questions or aspects of the study triggered distress, talking with a qualified clinician may help. If you feel you would like assistance please contact:

Dr Funmilola T. Taiwo, Department of Medicine, Ben Carson Sr. School of Medicine

Babcock University, Ilishan-Remo, Ogun State; E-mail: drloladetaiwo@yahoo.co.uk, Mobile: +2348059656752

OR

Olubunmi Ogunrin, Department of Health Services Research, Institute of Psychology, Health and Society, University of Liverpool, L69 3GL, United Kingdom (mobile phone: +447448839773, e-mail: olubunmi.ogunrin@liverpool.ac.uk OR Department of Medicine, University of Benin Teaching Hospital, PMB 1111, Benin City, Nigeria (mobile phone: 2348023344044, e-mail: bfunmi@uniben.edu)

Further Reading(s):

If you would like to learn more about '**Community engagement and informed consent process in genomic research**' please see the following references:

1. Tindana PO, Rozmovits L, Boulanger RF, Bandewar SVS, Aborigo RA, Hodgson AVO, Kolopack P, Lavery JV. (2011). Aligning community engagement with traditional authority structures in global health research: a case study from northern Ghana. *Am J Public Health*, 101(10): 1857-1867.
2. Rotimi CN, Marshall PA. Tailoring the process of informed consent in genetic and genomic research. *Genome Medicine* 2010; 2: 20 <http://genomemedicine.com/content/2/3/20>

*****Please keep a copy of this form for your future reference. Once again, thank you for your participation in this study!**