CONCEPTS OF COMMUNITY HARMS IN GENOMICS RESEARCH IN DEVELOPING COUNTRIES; A STUDY IN OYO STATE, NIGERIA.

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MATRICULATION NUMBER: 162436

NOVEMBER, 2011

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Matriculation Number: 162436

A dissertation in the Department of Surgery

Submitted to the Faculty of Clinical Sciences, College of Medicine,

in partial fulfilment of the requirements

For the award of degree of

Masters of Science in Bioethics

of the

UNIVERSITY OF IBADAN, NIGERIA.

NOVEMBER, 2011

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A DISSERTATION IN THE DEPARTMENT OF SURGERY, SUBMITTED TO THE FACULTY OF CLINICAL SCIENCES, COLLEGE OF MEDICINE,

UNIVERSITY OF IBADAN, NIGERIA.

IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF DEGREE OF MASTERS OF SCIENCE IN BIOETHICS.

BY

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ABSTRACT

Introduction:

Community harms are of particular concern in developing countries because genomics is a potent tool of exploring population history and understanding varying population incidences of certain conditions and response to treatments. Genomics can contradict communities' beliefs about its origins and relationship to neighbouring communities. There are also persisting political, tribal and ethnic conflicts in most developing countries which could be exacerbated by the result of genomics research, especially when unknown ancestry and predisposition to diseases are exposed. This study was designed to document information on the knowledge, attitude and perceptions of participants about community harms in general and harms from genomics research in developing countries in particular; the participants awareness of any instance of community harms in Nigeria; the knowledge of any local/international, ethical, legal, or social frameworks that address community harms; an how participants think that community harms can be prevented and remediated if they occur.

Methods:

Descriptive study involving the use of Focus Group Discussions (FGDs), Key Informant Interviews (KIIs), and In-depth Interviews (IDIs). "Purposive sampling" and snowball sampling method was used for the qualitative survey. Data were collected using audio recording devices and written notes, and analyzed manually using modified thematic analysis. The study populations were (1) male and female adult members of the Igbo-Ora community; (2) government officials and community religious/traditional leaders of the community; (3) ethics committee members who review research studies for Igbo-Ora and other places in Oyo State.

The data were captured in several themes; awareness and participation in genomics research; awareness and participation in other researches; concepts of harms in

researches conducted in Igbo-Ora; concerns about participation in genomics research; concerns about harms in genomics research; potential harms in genomics research in Oyo State; mechanisms and frameworks to protect community members that may be engaged in research; and mitigation of community harms and recommendations from survey participants.

Results

There was a low awareness of genomics research in Igbo-Ora; the people opine that they have neither participated in any, nor heard about any instance of harm due to genomics research elsewhere. They consider genomics research to be more sensitive than other forms of research for several reasons. They have participated in medical researches like malaria, guineaworm, onchocerciasis, yellow fever and hypertension researches. Some of the respondents reported that some physical injuries and psychological harms occurred to some research subjects in Igbo-Ora. These include the cases in the malaria study, where "some farmers developed whitlow", and the outcome of the guineaworm research in which some villagers felt insulted with the pattern of borehole construction for the people; there were also complains about the contamination of the community's water bodies by chemicals used by the guineaworm researchers. For the hypertension studies, it was reported that some research subjects suffered various complications at the end of the study because of the non-continuance of their treatment. Respondents alleged that the research subjects were not properly educated on the need for them to seek further medical attention after the cessation of the study.

The respondents were concerned about the potential community harms due to research, which they conceptualized as assault on one's dignity, injury, neglect, offence,

poisoning and provocation, endangering life, deception, insult, extortion, communal conflicts, defamation, destabilization of families, disgrace, dishonour, discrimination, exploitation, and stigmatization. There was low awareness on the ethico-legal frameworks to avert community harms, among the study participants, but they suggested that to prevent community harms from genomics research, there should be adequate community consultation (involving the enlightened members of the community) before and during the process of carrying out the research. They also demanded that sensitive research results that could ridicule the family or community, should only be published by researchers after due consultation with the community leaders.

Discussion:

There was little awareness of genomics research among the Igbo-Ora community. This is surprising, and may be due to focus on the health related themes of the research rather than the genomics part. For example in a genomics of hypertension research, community members may focus on the hypertension. There was generally a high level of trust in, and acceptance of medical research by the people of Igbo-ora and Oyo state. This study shows that some members of the community had individual harms due to research, but there was no report of group harms. All the instances reported represent the varied forms of harms (physical, psychological, social, economic, and dignitary,) apart from legal. The perceptions of harms as revealed in this study reflect the opinions of the survey respondents individually, and may not represent the formal position of the community.

The people did not have concerns related to the consenting process, perhaps due to the reduced influence of individualism on the society. Getting informed consent is

important to them but it is not in the context of the traditional ethical principle of individual autonomy. Once the leaders, family heads and enlightened people are consulted, and they inform the villagers and the head of the households, adequate consenting is considered consummated. The research participants' demand to be consulted before potentially stigmatizing data is published is primarily to avert community harm. This and other recommendations could as well apply to other communities in the developing countries.

KEYWORDS: Genomics, community, harms, stigmatization, exploitation, discrimination, Igbo-ora, Yoruba, Nigeria.

ACKNOWLEDGEMENT

This research project has indeed become a huge success, courtesy of many people's contributions. I am amazed with the level of support I got from my supervisor, Prof. Clement Adebayo Adebamowo, who not only conceptualized the study, but painstakingly guided me through each step of the project.

The people of Igbo-ora were so wonderful; they participated in the study in such a way that made a lasting impression on me about how best to involve and engage African communities in research. I am also indebted to my lecturers and other members of the WAB faculty for their invaluable support in the process of this study.

All my friends and family members are keenly appreciated. I drew a great deal of inspiration from them throughout the course of the program.

This research which forms part of the requirement for my Masters degree in Bioethics at the University of Ibadan was made possible by Grant Number D43 TW007091 and 3R25TW007091-06S2 from the United States' National Institutes of Health's Fogarty International Centre and the National Human Genome Research Institute. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the awarding office of the NIH/Fogarty International Centre.

CERTIFICATION PAGE

I hereby attest that this research project was carried out by Dr Maduabuchi John-Moses Uwanduoma, of the Bioethics Unit, Department of Surgery, Faculty of Clinical Sciences, University of Ibadan.

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DEDICATION

To my beloved mother, Dame Benedette Nnenna Ugwuona and Prof Ifeoma Joy Okoye, Chairperson, Association for Good Clinical Practice in Nigeria.

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GLOSSARY OF ABBREVIATIONS

AHRQ – Agency for Healthcare Research and Quality.

BRCA1 – Breast Cancer Gene-1.

CAC – Community Advisory Committee.

CBPR – Community Based Participatory Research.

CRWG – Community Recommendations Working Group.

EFA – Education for All.

IRB – Institutional Review Board.

MalariaGEN – Malaria Genomic study ongoing in Kenya.

MTA – Material Transfer Agreement.

NHREC – National Health Research Ethics Committee.

NIH – National Institutes of Health.

SBES – Social and Behavioural Science.

OHSR – Office of Human Subject Research.

CHAPTER ONE

BACKGROUND

Historically, community harms have been of great concern especially for some countries. When most people think of group harms, they remember the Ashkenazi Jews, whose experience show that when the socio-demographic traits of a community are altered, the level of risk of group harm attributable to them could change. (Hausman 2007). The commonest harms that communities have complained about include the mining of their DNA and other genetic information for reasons that were never disclosed to them. (Sterling 2011). The Paoakalani Declaration written by Native

Hawaiians is one of the most apt illustrations of concerns of community harms in genetic research. In this declaration, the activities of the bioprospecting and biotechnology institutions and industries in imposing western intellectual property rights over traditional, cultural land-based resources, and the use of biogenetic materials obtained from people through misrepresentation, and without informed consent were decried as biopiracy and acts of biocolonialism. (Santos 2010).

1.1 Statement of the problem:

Community harms emanating from genomics research are of particular concern especially in developing countries because genomics is a potent tool for exploring population history and understanding varying population incidences of diseases and response to treatments. Genomics for example can contradict communities' beliefs about their origins and relationships to neighbouring communities. There are also persisting political, tribal and ethnic conflicts in most developing countries which could be exacerbated by the result of genomics research, especially when unknown ancestry and predispositions to diseases are exposed. Community harms especially as may arise from genomics research have not been widely studied in Africa.

1.2 Justification/rationale for the study:

There is limited knowledge about community harms arising from genomics research throughout the world. However, in recent times a high-profile case of group harm was reported, among the Havasupai, a Native American tribe in Arizona. In the 1990's Arizona State University (ASU) researchers collected DNA samples from members of the Havasupai tribe with the intention to look for gene variants associated with diabetes, a common and serious disease among the tribe's members. For this study the participants consented to give blood to the researchers because they believed they

'might get a cure' for diabetes, not minding the spiritual significance they ascribe to their blood. (Lowenberg 2010). Unfortunately, the members of the tribe learned that the ASU researchers who had gathered blood samples from them to search for a link to diabetes also used the samples to look for other diseases and genetic markers. (Sterling 2011). The samples were actually used to study schizophrenia, the tribe's origin, and their degree of inbreeding. The Havasupai filed a lawsuit alleging that these additional studies exceeded their informed consent. The contention in this case was that the Havasupai community was exploited, deceived and exposed to untold group harm by virtue of the series of studies conducted using their blood without their permission and for the fact that such studies generated results which threatened the very essence of their existence and ancestry. They did not believe the findings to be true and acceptable as they negated their traditional history and basic tenets of life. In the legal battled that ensued they also argued that the manner in which researchers used their people is unethical, irrespective of the acceptability of community research by their tribe. (Lowenberg 2010).

Among the scientific research community, the paradigm of community-based participatory research (CBPR) has been promoted to avert potential harms to groups of people. The Agency for Healthcare Research and Quality (AHRQ) defines CBPR as a "collaborative research approach that is designed to ensure and establish structures for participation by communities affected by the issue being studied, representatives of organizations, and researchers in all aspects of the research process to improve health and well-being through taking action, including social change" (Viswanathan 2003). CBPR, also entails shared decision-making power and mutual ownership between the community and the researchers. (Minkler 2005). In conducting CBPR, certain fundamental principles apply regardless of the group in question. It is vital that a

researcher respect the community and its values and beliefs and follow the principles of human subject research, which include obtaining informed consent from the community. This is necessary to avoid offences to community, and problems of credibility to the researcher or institution. (Sterling 2011). This study was necessary sought to seek the participants' values and belief systems which could help in preventing community harms. As it has been shown in the case of the Havasupai, most of the relevant expectations especially those of respect for the values and belief systems of the communities and obtaining valid informed consent were not met. The Havasupai believed their blood samples and DNA would only be used to study diabetes, but the written consent form they signed included a very broad statement about how DNA samples would be used to study the causes of behavioural/medical disorders. (Lowenberg 2010). This situation gave the researchers the leeway to use the samples for studies that were not anticipated by the people resulting in the legal case that was based on a six-count charge that included lack of informed consent, violation of civil rights, and intentional or negligent infliction of emotional distress. (Harmon 2010).

Across Africa and in other developing countries, there are many tribes that are more or less impoverished like the Havasupai. The features of developing countries predispose their citizens to an increased risk of research harms in general, and to community harms particularly, especially in genomics research. Developing countries are unfortunately characterized by high illiteracy rates, AIDS, poverty, gender inequality, general poor health indices, and myriads of political, tribal and communal conflicts. Moreover, for these countries, even the prospects of benefiting from the Millennium Development Goals (MDGs) as expected are also questionable. The MDGs encompass (and address) not just education but also health, AIDS, poverty, gender equality and other basic human needs or rights. For literacy, two basic indicators

are used, (a) the youth literacy rate – as for Education for All (EFA); (b) the ratio of literate females to males for 15-24 year olds. (Terry 2010). The Nigerian situation typifies this description; the 2003-2006 Demographic and Health Survey reports put Nigeria's adult literacy rate (2003) at 55 per cent. This figure is low when compared with Zimbabwe's (2005-2006) 84.5 per cent, Lesotho's (2004-2005) 79.4 per cent and Cameroon's (2004) 62.5 per cent. Literacy is also hobbled by the low value accorded by parents to girls' education. Other obstacles to high literacy rate include early marriage, poverty, local beliefs, and norms that impact negatively on girl child education. Surprisingly, the 2007 EFA Global Monitoring Report indicates that the country has 63 per cent illiteracy rate and that it is among the 12 countries, which harbour three quarters of the world's illiterate population. The EFA also says there is a high disparity between female and male literacy. (Punch Ed. 2009). People living under these conditions feel precarious and are always vulnerable to exploitation when it comes to healthcare research and services delivery. There are also peculiar disease patterns among some developing countries which have predisposed some communities to exploitation and group harms. This study was deemed necessary to assess the perception of these risks and the extent of group harms (if any) from genomics research.

The advent of genomics research in developing countries occasioned the need for this study on the concepts of community/group harms especially in Nigeria where no such research has been conducted. Discovering the perceptions of people in this part of the world with a view to determining the safe approaches to the conducting of genomics research, that would be sensitive to, and not negligent of the traditional belief systems is considered timely in this era of genomics. The findings of this study have contributed to the knowledge about the ethical conduct of genomics research in developing countries. The results have also increased knowledge about community

beliefs, informed genomics research, researchers and research regulators, especially the ethical review committees on how to guard against community harms through more culturally sensitive means.

1.3 Research Questions:

1. What are the knowledge, attitude and perceptions of actual and potential research participants about community harms in general and harms from genomics research in developing countries in particular?
2. Are actual and potential research participants aware of any instance of community harms in Nigeria?
3. Are there any known local or international, ethical, legal, or social frameworks that address community harms?
4. How do participants think that community harms could be prevented and if they occur, how could they be remediated?

1.4 Objectives of the Study:

The broad goal of this study was to explore the meanings, the impact and awareness of community harms within the context of genomics research among health research stakeholders in Nigeria and to explore how best to mitigate the risks of community harms due to genomic research in developing countries.

1.5 Specific Objectives:

1. To ascertain the knowledge, attitude and perceptions of actual and potential research participants about community harms in general and harms from genomics research in developing countries in particular.

2. To ascertain if actual and potential research participants are aware of any instance of community harms in Nigeria.
3. To establish if there are any known local or international, ethical, legal, or social frameworks that address community harms.
4. To discover participants' opinion of how community harms can be prevented and if they occur, how they could be remediated, especially in developing countries?

1.6 Basic Concepts and Definitions:

1.6.1 Community and Dignitary Harms:

The definition of the word community could be debatable (Hawkins 2008) as the term community delineates a wide variety of human associations, from tribes to municipalities to religious adherents. (Weijer 2000). Community harms entail injuries, whether emotional, physical or dignitary harms that may result to groups of people that share a common geographical location, or socio-cultural identity. In common law jurisdictions a tort is a wrong that involves a breach of a civil duty owed to someone else. Dignity on the other hand has different concepts and played significant roles in decisions around the world in the adjudication of civil rights and liberties. (Rao 2011). Dignity "as a fundamental precept of human rights and basic liberties", really took hold after the Universal Declaration of Human Rights which states that "all human beings

are born free and equal in dignity and rights." (Rao 2011). It is very obvious that 'dignity' is an important yet slippery concept. In the legal literature, there is a low understanding of how the various concepts of dignity reflect different underlying conceptions of individual rights within a community. Experts have argued that the differences are more than philosophical or semantic disagreements; that different conceptions of dignity have important practical consequences for the understanding and adjudication of rights. In constitutional law, dignity has been described in three concepts; Inherent dignity, substantive dignity and dignity as recognition. Inherent dignity is further illustrated with dignity as intrinsic human worth, inherent dignity and negative liberty and dignity as intrinsic worth in judicial decisions (Rao 2011). In legal proceedings, intrinsic dignity is reflected in decisions about freedom from interference by the state in areas such as freedom of speech, privacy, and sexual relationships. On this view, restraint or removal of state interference maximizes dignity because it leaves the individual free to exercise his autonomy in whatever fashion he should choose consistent with the rights and freedoms of others. Dignity as an intrinsic human worth exists merely by virtue of a person's humanity and does not depend on intelligence, morality, or social status. Intrinsic dignity is a presumption of human equality—each person is born with the same quantum of dignity. Unlike intrinsic dignity, substantive forms of dignity require living in a certain way. Dignity may require behaving, for example, with self-control, courage, or modesty. (Rao 2011).

Dignitary harms are essentially dignitary torts. Historically, the primary dignitary torts were battery, assault, and false imprisonment as each, claimed harm to a person's human dignity. Under modern jurisprudence, the category of dignitary torts jurisprudence is more closely associated with secondary dignitary torts, most notably defamation (slander and libel), false, light, intentional infliction of emotional

distress, invasion of privacy, and alienation of affections. The concept of community harm in genomics research agrees more with these secondary dignitary torts. Community harm and group harm refer to the same issues and have been used interchangeably. But "there is a difference between group harms and group-mediated harms. The crucial characteristic of group-mediated harms to individuals is that they occur in virtue of beliefs about certain traits of individuals or their membership in a group characterized by those traits. Groups are causally important to group-mediated harms, and it is thus important to study them and to understand their role. But in group-mediated harms, groups, as opposed to their members, are not *ipso facto* themselves of ethical concern". (Hausman 2008).

A group or some trait that defines a group may play an important role in causing individuals to be subject to risks or harms and hence in explaining why some research findings create harms or risks to individuals. Such harms to individuals count as group harms, because the individuals suffer harm because of or in virtue of belonging to certain groups. Harms to individuals by virtue of their group affiliation are group harms in the sense that group membership explains the individual harms, not in the sense that the group itself, in distinction to its members, is harmed. Thus the attempts to classify group harms into harms to individuals in virtue of their membership in groups and harms to 'structured' groups that have a continuing existence, an organisation, and interests of their own. There are two ways in which groups can be morally significant. Either, groups play a role in causing harms or benefits to individuals, or groups themselves can be harmed or benefited. (Hausman 2008). These issues are of importance, not only to the researchers but also to the community partners who often have specific interests related to the outcome of research. Most communities have an

interest in publishing research about the community, but also have an interest in protecting the community from adverse publicity, stigma, discrimination, and other harms that could result from the publication of findings that report medical or social problems in the community, such as HIV/AIDS, alcoholism, prostitution, cancer, genetic diseases etc. (Resnik & Keneddy 2010).

1.6. 2 Genetics and Genomics:

Genetics is the scientific study of the ways in which different characteristics are passed from each generation of living things to the next. Genomics on the other hand is a discipline in genetics concerning the study of the genomes of organisms. A medical test for instance could be used to detect if a particular disease exists in an individual and if the disease was transmitted to the person from his or her parents based on available knowledge. If such test does not involve accessing the information from the person's genetic composition, it could still be referred to as a genetic test because it reveals genetic information but does not qualify for a genomic test. Genomics as a field includes intensive efforts to determine the entire DNA sequence of organisms and fine-scale genetic mapping efforts. Thus even when researchers have defined objectives in conducting genomics studies or tests, they invariably stumble across other information contained in the genomes of the subjects which could be used in ways that may be harmful or beneficial to the subject. Obviously, genetics has a wider scope than genomics but for the purposes of this study, both will be used to mean the same thing.

CHAPTER TWO

LITERATURE REVIEW

2.1 Genomics Research:

The WHO described community genetics as the art and science of the responsible and realistic application of health and disease-related genetics and genomics knowledge and technologies in human populations (communities) to the benefit of individual persons. (WHO 2010). Although the emphasis here has been rightly on the responsible and realistic application of genetics and genomics, our focus as researchers should not only be on benefits of individual persons but include that of the communities involved in research as well. Genomics is a new science which endeavours to chart the genomes of individuals around the world, with the dual goals of understanding the role genetic factors play in human health and solving problems of disease and disability. (Jacobs 2011). Popular genomics studies include the Genome-Wide Association Studies (GWAS) and, more recently, projects that make use of next-generation sequencing. Over the past 5 years, GWAS have proven very valuable in

identifying regions of the genome that affect resistance or susceptibility to a wide range of common diseases. (de Vries 2011). GWAS examine associations between genetic variants (genotypes) throughout the human genome and observable traits, such as height, cholesterol levels, or disease (phenotypes). (Lemke 2011). GWAS undoubtedly have many key ethical challenges which have only been identified fairly recently. Pertinent issues like consent and privacy concerns in GWAS remain relevant topics of debate (P3G Consortium 2009), and consensus about the best approach to accommodate these challenges in research has not been reached. (de Vries 2011).

The first publication of the human genome sequence in 2001 marked the dawn of the 'Post-Genome Era' and led to a new public awareness of genetics and genomics (Lander 2001; Venter 2001). The data generated by these projects were the DNA sequence of a handful of individuals, as they were not designed to capture the diversity of the human genome. Concurrently with sequencing projects, efforts were underway to capture this diversity by sampling the DNA of many people from distinct geographic locations. The approaches to ethical, legal and social implications (ELSI) of these projects differed, as did their success at interacting with indigenous peoples and residents of developing countries. In some cases, genomic scientists and local communities have effectively collaborated, but in others, work has yet to commence. (Cavalli-Sforza 2005). This could be due to several reasons including the challenges of community engagement. In the field of biomedical ethics, community-researcher partnerships constitute one of the most important recent developments. Such partnerships protect vulnerable communities within which research is conducted and help ensure that the communities benefit from the research. (Wallwork 2008). This is more theoretical than practical, as it has been shown that collaborations and multi-

national partnerships in genomics research are fraught with potential harms to individuals and communities especially. In a recent study reported from the Institute of Human genomics, University of Miami Florida, study participants discussed topical issues about genomics research. Among the common concerns raised were the lack of affordability, unanticipated physical harm, mistrust of the government and researchers, downstream effects like overpopulation, playing God/disturbing the natural order, lack of regulations, loss of privacy, genetic discrimination, and moral dilemmas posed by genetic engineering, cloning, choosing traits, and abortions resulting from genetic information. (Hahn 2010).

In addition to its role in improving knowledge about diseases, genomics is a potent tool of exploring population history and understanding varying population incidences of certain conditions and response to treatments. (Adebamowo 2011). An increasing amount of information about genetic variation, together with new analytical methods, is making it possible to explore the recent evolutionary history of the human population. (Sabeti et al. 2007). Genomics can also contradict communities' beliefs about its origins and relationship to neighbouring communities. Genetic research differs from other types of medical research because of culturally embedded beliefs about heredity even as inherited genetic traits cannot be changed. Moreover, results of genetic research may reinforce racist stereotypes or result in discriminatory practices against individuals or populations. (Marshal et al. 2006). For this reason, no genomics research may be characterized as minimal risk research because of the likelihood of community harms and other subtle risks. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (OHSR 2011).

The risks of genetics research and the proposal to address them by group engagement are very complicated, because they result from both the research process and from the research findings. (Bok 1979; Hausman 2007). Nevertheless, the principles of community-based participatory research (CBPR), are becoming more widely adopted by Native communities, and require that research: 1) address health of the community within its broader cultural, social, economic, and political context; 2) involve community at all levels, from priority setting and planning to interpretation and dissemination of findings; 3) identify community needs and concerns that need to be addressed; 4) build on the strengths and resources within the community; 5) promote co-learning and knowledge transfer; and 6) provide tangible benefits to the community. (Fong 2003). Notwithstanding its importance, the actual achievement of successful and appropriate community engagement activity presents a number of practical and ethical challenges; An example of these challenges relate to the question of how the relevant community is to be identified and represented. (Marsh 2008; Tindana 2007). There could also be conflicts between scientific and community interests which could be managed by both parties entering into written agreements at the beginning of the study. In some cases it may be necessary for a third party, such as a review committee from a supporting institution, the community, or a funding agency, to help investigators and community partners resolve disagreements. (Resnik 2010). Viable collaborative partnerships and attainment of social value have been proposed as benchmarks against which the ethics of research in lower income countries should be measured. (Emanuel 2004; Lavery 2008). This is in recognition of the need for locally relevant health research in lower income countries, and by awareness of the potential for exploitation in contexts of vulnerability and inequality (Nuffield 2002). Although genomics research offers the possibility of improved technologies for managing the acute and

chronic diseases that plague their members, yet, the history of biomedical research among people in indigenous and developing nations offers salient examples of unethical practice, misuse of data and failed promises. (Jacobs 2011).

2.2 Ethical Challenges of Genomics Research:

Genomics research raises a number of ethical challenges wherever it is carried out (Kaye 2010; Caulfield 2008.) Various researches into the genetic differences among human groups has been controversial because of the intrusion of researchers into indigenous communities and because of the risks it creates of stereotyping, discrimination, weakening group identity, or undermining group claims and goals (Hausman 2008). An increasing number of GWAS is taking place in lower income countries and there is a pressing need to identify the particular ethical challenges arising in such contexts. (de Vries 2011). These include the research communities' predisposition to group harms and the lack of adequate systems to address them. The situation is more daunting from the perspective of indigenous peoples and developing countries, for which the promises and perils of genomics science appear against a backdrop of global health disparity and political vulnerability. (Jacobs 2011). It has even been argued that whilst many studies have taken place focusing on a wide range of conditions, hardly any genomics study has been applied to diseases that primarily affect people in lower income countries. (Rosenberg 2010; Need 2009). The application of the methods of genomics research to these diseases is one way to address the imbalance of substantial global inequalities existing in health measures such as mortality, quality of life and disease incidence. (de Vries 2011). Some argue that the history of poor scientific and ethical practice justifies refusal to join genomics research projects. Thus, some communities particularly among indigenous peoples have declined to participate as subjects in genomics research. (MacIntosh 2005). Indeed,

many indigenous organizations and communities have already decided not to participate in genomics research citing negative experiences with earlier projects such as the Human Genome Diversity Project (HGDP), the National Geographic Genographic Project, and others. (Reardon 2005; Tallbear 2007). Contrarily, others argue that diseases pose such great threats to the well-being of people in indigenous communities and developing nations that not participating in genomics research risks irrevocable harm. From the perspective of the ethical, legal and social issues (ELSI) facing genomics research, bridging the gap between indigenous people and genomics scientists offers lessons and models for conducting genomics research for the world community as a whole, particularly for vulnerable and high risk populations. de Vries and her colleagues reported that the ethical issues in genomics research can best be identified, analysed and addressed where ethics is embedded in the design and implementation of such research projects. (de Vries 2011).

2.3 Potential community harms in genomics research:

Conventional wisdom assumes that human subjects participating in medical research generally face significant risk of pain, disability, and death. In fact, evidence suggests that, in the aggregate, research subjects fare as well therapeutically as patients with similar conditions not participating in clinical trials. Research subjects, however, face unappreciated risk of intangible harm, even if not physically injured. Such intangible hazards include frustrated access to investigational technology, affront to dignitary interests, and participation in a study that fails to disseminate meaningful data in order to advance medical knowledge. (Saver 2006). Physical harms include discomfort, injury and death but psychological harms, such as distress, anger, or guilt, can also result from disclosure of sensitive or embarrassing information collected in

the research. The harms that could be faced by individual research participants include not only emotional distress, but also economic harms like lost opportunity costs, destruction of trust and confidence in the research process. (Saver 2006). These all constitute in "intangible harm". According to the final report of the National Bioethics Advisory Commission (NBAC; 2001:71-72), there are six types of harms that can occur to research participants: physical, psychological, social, economic, legal, and dignitary. (Constance 2003).

1. **Physical harm** from research can include death, injury, pain, suffering, or discomfort. Examples in biomedical research range from death due to an experimental drug administered in a cancer study to discomfort from having to keep still for a long time during an MRI (magnetic resonance imaging) study.
2. **Psychological harm** from research can include negative self perception, emotional suffering (e.g., anxiety or shame), or aberrations in thought or behaviour (e.g., agreeing to a hateful statement under pressure from the research environment). In both biomedical and SBES research, psychological harm from the research procedure can range from momentary anxiety or embarrassment to long-lasting, intense psychological distress and fear, which could in extreme cases result in suicide. A biomedical example is when a participant in a genetics study learns that he or she is likely to develop a disease for which there is no treatment or cure.
3. **Social harm:** can involve negative effects on relationships or interactions with other people. Such effects are most likely to result from a breach of confidentiality, in which a participant's answers become known to others. Examples of social harm include discriminatory behaviour resulting in loss of insurance or employment from knowledge of study results (e.g., that one has or

is likely to contract a specific disease). Stigmatization is another social harm that can result from knowledge about a person's participation in a study or particular findings.

4. **Economic harm** usually involves financial loss, which can result from study participation (e.g., the need to pay for transportation or childcare in order to participate), from disclosure of study findings or participation (e.g., loss of health insurance or employment), or as a side effect of other harms (e.g., having to pay court costs in a lawsuit that results from a breach of confidentiality).
5. **Legal harm** can include arrest, conviction, incarceration, and civil lawsuits. Such harm can result, for example, from a breach of confidentiality in studies of possession or use of illegal drugs, sexual abuse, or shop lifting behaviour, or in situations in which state law requires that certain types of researchers report particular activities, such as child abuse.
6. **Dignitary harm** can result when individuals are treated as means to an end and not as people deserving respect for their own values and preferences. Such harm can happen in studies that do not appropriately obtain informed consent.

The recognition of a dignitary right for research subjects could be a promising vehicle for bringing various claims for intangible harm relief, as dignitary concerns may arise independent of physical injury and even emotional distress. Whether research subjects, have a viable enforceable legal claim, to be treated with dignity remains unclear. However, several commentators assert that research subjects have such a right based on more general assertions of inalienable rights, without providing a concrete legal source for recognizing such claims. (Saver 2006). Dignitary harms are not the only potential hazards for communities engaged in genomics research: Authors have opined that many of the potential harms and benefits of genomics research relate to populations

rather than to individuals (Lowrance 2007). There is a need to further evaluate if this is an important feature of genomics studies for communities and participants, and how it could best be explained and discussed. (de Vries, 2011). Harms like exploitation, social/racial prejudice, discrimination, and stigmatization make research very difficult and harmful to both individuals and societies. (CRWG 2009).

D. Stigmatization:

Information produced by genomics research has, for example, the potential to be informative about people other than the research participants. There has been much discussion about the importance of privacy protection for individual research participants in genomics studies (Gitschier 2009; Nyholt 2008; P3G Consortium 2009). Where personal identifiers are removed from genomics datasets there may arguably be limited risk of participant identification. Yet even where this is the case, there remains a possibility that unwanted information about populations, communities or families will be revealed. At the population level, GWA studies have for example the potential to reveal that a stigmatizing condition is more likely to occur in one population than another (McGuire 2008). In that sense, it raises the possibility that genomics data could be used in ways that would have adverse effects for the populations involved, possibly through generating research results that could be used to stigmatise groups based on their genetic make-up (Koenig 2008; Ellison 2002).

E. Exploitation:

The starting point of all human subject research is the assurance that trial participants will be protected from exploitation. (Karim 1998). In clinical trials for instance, unless the interventions being tested will actually be made available to the impoverished populations that are being used as research subjects, developed countries are seen to be simply exploiting them in order to quickly use the knowledge gained from the clinical

trials for the developed countries' own benefit. (Annas & Grodin 1998). The concerns about exploitation are not limited to clinical research in developing countries. Exploitation is a potential concern in all clinical research all over the world. All research 'uses' the participants to gain information that, hopefully, will improve the health of others whether directly, or indirectly through additional research. (Hawkins 2008). Having said that, it is not and over-emphasis to say that the central issue in doing research with impoverished populations is exploitation. (Annas 1998). By itself, exploitation is a diffuse and unclear ethical concept. Why is exploitation itself vague and unclear? The problem stems both from the fact that exploitation can be used in morally loaded and morally neutral ways, and from the fact that we often fail to realize that not all 'use' of people, despite sounding bad, is morally problematic. (Hawkins 2008). Exploitation is the common concern with poor standard of care, unsound study design, invalid informed consent, and absence of reasonable availability and/or fair benefits for research participant. By placing some people at risk of harm for the good of others, clinical research has the potential for exploitation of human subjects. Ethical requirements for clinical research aim to minimize the possibility of exploitation by ensuring that research subjects are not merely used, but are treated with respect while they contribute to the social good. (Emanuel 2000).

We are in the era of increased commercialization of research outcomes, when medical centres and investigators may be tempted to side-step research subject protection, particularly regarding easily overlooked intangible hazards. Financial conflicts of interest may also exacerbate intangible harm by eroding trust in clinical research generally, (Boddenheimer 2000) as well as engendering perceptions of subject betrayal and exploitation for other parties' commercial aims. (Saver 2006). These concerns are more pronounced with some categories of research participants who may

be more vulnerable to exploitation. This is the case with children for instance, because they are largely dependent on others for their well-being and for protection. They have less power, knowledge, education, resources and strength than adults do, they are more susceptible to coercion, harm, exploitation, deception or unfair treatment. In some communities, children may also be subject to harmful cultural and gender norms that increase their vulnerability to exploitation, physical and psychological violence, illness and disease. (WHO 2004).

Communities and individuals in developing countries could be exploited in genomics research, as may be occasioned by their vulnerability due to poverty, low literacy rates, general poor health indices, and myriads of political, tribal and communal conflicts. According to Lurie, residents of impoverished, postcolonial countries, the majority of whom are people of colour, must be protected from potential exploitation in research. Otherwise, the abominable state of health care in these countries can be used to justify studies that could never pass ethical muster in the sponsoring country. (Lurie 1997). All these situations need to be considered on their own merits, applying ethical principles in a way that protects individuals and communities from exploitation. (WHO 2004).

F. Discrimination:

Discrimination could refer to a positive or negative attitude toward an individual based on his or her membership in religious, racial, ethnic, political, or other groups. In the west, racial prejudice and discrimination have been of prime concern. The problem of racism and racial discrimination is evident not only in health status, but also in health care and in health care research, especially genomics research. (Randall 2001). Racial discrimination is both overt and covert and it takes two closely-related forms:

- individuals from racially privileged groups acting against individuals from racially disadvantaged groups, and acts by racially privileged community or country against racially disadvantaged community or country which has the intent of maintaining privilege;

- policies, practices, regulations and laws that, when implemented, have a disparate negative impact on individuals from racially disadvantaged groups, communities or countries. (Randall 2001).

It has been stated that most communities have an interest in publishing research about the community, they also have an interest in protecting the community from adverse publicity, stigma, discrimination, and other harms that could result from the publication of findings that report medical or social problems in the community, such as HIV/AIDS, alcoholism, prostitution, cancer, genetic diseases, etc. (Resnik 2010). Discrimination could be an 'unthinking discrimination' which results from acting on biases and stereotypes and does not involve an overt actual desire to discriminate. (Randall 2001). This can commonly occur in genomics research; the outcome of a research could lead to discrimination against a community or group of people. There should be legal activities to prevent racial discrimination in Health Care and Health Research. These should be informed by perceptions of communities engaged in research especially in developing countries.

2.4 Possible Solutions to Community and Dignitary Harms from Genomics Research:

In the United States of America, many thorny questions of how to account for intangible harm arising from research currently challenge the courts, regulatory agencies, and legislatures. In several recent lawsuits, subjects have raised relatively

novel allegations about violation of 'dignitary rights'. Other recent disputes have involved subjects' seemingly incongruous claims of harm arising from study terminations that denied them access to experimental technology and treatment. (Saver 2006). Nigeria has not witnessed these sorts of legal challenges but it would be safer to pre-empt them by the utilization of appropriate preventive measures. Another question that has been asked is whether the intangible hazards faced by subjects should be cognizable to a greater degree. It has been recommended that employing more flexible approaches has considerable advantages, including strengthening the needed respect for subjects as persons with individual dignity, remedying problematic informed consent, policing opportunistic conduct in the investigator-subject relationship, and promoting trust in research, which in itself is an independent, socially important goal. (Saver 2006.) Recommended approaches for the mitigation of harms from genomics research include:

2.5 Community Engagement in genomics research:

Recent history of genomic research among indigenous peoples and developing countries across the world, demonstrate the need for researchers and communities to cultivate trust prior to the initiation of research. (O'Niell 2009). An adequate community engagement helps realize this and enables researchers to take account of staff and community opinions and issues during the study and adapt messages and methods to address emerging ethical challenges. (Marsh 2010). A community engagement strategy (through a series of consultative activities) was recently employed in Kilifi (Kenya) to strengthen mutual understanding between community members and the research centre. One important component of this engagement process is the establishment of representative local resident networks in different geographic locations commonly involved in research, to supplement existing channels of

communication. (Marsh 2008). Consent for genetic research is seen as particularly sensitive because it may have consequences for family members beyond the individual. Indeed, the research may only be possible if multiple members of the same family participate. (Beskow et al. 2004). These issues are better addressed at the initial engagement contact. In response to the traditional emphasis on the rights, interests, and well-being of individual research subjects, there has also been growing attention focused on the importance of involving communities in research development and approval. Early and on-going community consultations are particularly common methods of involving communities throughout the tenure of a research project. Recently, there has been an increasing interest and promotion of community engagement in Nigeria. Addressing the capacity needs of laypersons on ethics committees has been recommended as an important way of promoting community engagement in research. (Ukpong 2011). However the fundamental ethical goals of community consultation have not been delineated, which makes it difficult for investigators, sponsors, and institutional review boards to design and evaluate consultation efforts. Community consultation must be tailored to the communities in which it is conducted, but the purposes of consultation—the ethical goals it is designed to achieve—should be universal. (Dickert & Sugarman 2005).

The issue of the need, justification, and implementation for group consent has been raised in medical and health care research, particularly in genomics research, as well as for non-medical and behavioural science research. (Schrag 2006); researchers in the social sciences are generally slow in identifying with the need for informed, individual voluntary consent. Some were unaccustomed to thinking about informed consent at all and so now confront increasing demands for group consent from a much different perspective than those in medical ethics. (Fluehr-Lobban 2003). The concept

of voluntary consent of individuals in health research is more traditional than the issue of group consent. It also appears that the much emphasis given to individual autonomy as a key ethical principle especially in the western countries made it more difficult for some researchers to promote the idea of group consent. Group consent in general, is most likely to give appropriate weight to the values of the community. (Schrag 2006). According to the Nigerian national code for health research ethics published by the National Health Research Ethics Committee (NHREC), Federal Ministry of Health, ethical research must ensure fair selection of participants based on the scientific objectives of the research while minimizing risk of research. Groups, communities, participants and researchers who bear the burden of research should share in the benefits as well. In certain instances, community consultation or assent may precede research activities in order to engender community buy-in, respect for the socio-cultural values of the community and its institutions. It may also be necessary to inform the community from time to time about the progress of the research, pertinent findings that may influence their health and wellbeing, and, the outcome of the research. (NHREC, 2006).

In addition, Dickert and Sugarman proposed four (4) ethical goals of community consultation (engagement): (1) enhanced protection, (2) enhanced benefits, (3) legitimacy, and (4) shared responsibility.

Enhanced protection: Enhance protections for subjects and communities by identifying risks or hazards that were not previously appreciated and by suggesting or identifying potential protections.

Enhanced benefits: Enhance benefits to participants in the study, the population for which the research is designed, or the community in which the study is conducted.

Legitimacy: Confer ethical/political legitimacy by giving those parties with an interest or stake in the proposed research the opportunity to express their views and concerns at a time when changes can be made to the research protocol.

Shared responsibility: Consulted communities may bear some degree of moral responsibility for the research project and may take on some responsibilities for conducting the study. (Dickert & Sugarman 2005).

2.6 Regulation and review of genomic research in developing countries:

The principal ethical standards for community genetics services, genomics research (as well as all human subject research) are based on maximizing benefit, minimizing harm, respecting privacy and autonomy and ensuring equity (WHO 1998; WHO 2006a; WHO 2006b; Ten 2010). Ensuring these situations are obtained is the primary duty of the ethics review and regulatory systems. The system of regulation of human genomics research can contribute to the mitigation of community harms in developing countries. Where genomics research focuses on diseases affecting populations with lower average income and literacy levels, it tends to take place in collaborations between researchers from higher and lower income countries, so regulatory frameworks that are acceptable across international boundaries would apply. For example, whereas the infrastructure for genotyping and whole genome analysis is usually based in higher income countries, the patients affected by the diseases are based in lower income countries. This distribution of research resources raises important issues about the use of archived samples, sample ownership and ethics review by multiple committees. Multiple ethical reviews involving ethics committees in different countries have been recommended so as to accommodate diverse cultural variations and levels of exposure to harm that may be associated with the communities involved

in the study. (de Vries 2011) Some of the ethics committees reviewing genomics research especially in developing countries may also not have had the training or requisite experience to enable them to identify and analyse the key ethical issues. (Kass 2007; Kass 2009; Nyika 2009). This supports the idea of multiple ethical reviews. Notwithstanding, one of the arguments against multiple ethical reviews is the cost in terms of time and manpower involved in reviewing a research protocol. For international collaborative research projects for which ethics approval is needed to be obtained from a multitude of committees around the world, the task could be very daunting, especially where committees express different or conflicting points of view or place additional requirements on the researchers. (Glasziou 2004). Although it is well-recognized that ethics committees reviewing research in many other research fields may not as well have adequate training or experience, (Kass 2003, Kass 2007 and Nyika 2009) genomics research raises peculiar challenges that may not be familiar to many existing ethics committees (de Vries 2011). All consortia proposing genomics researches should create enough avenues for ethics committees to build adequate capacity for the review of such researches. It has also been suggested that review of genomics research should also not be left for conventional ethics committees alone, but for special boards that have been demonstrated to have the required capacity. Special and well-trained ethics committees are actually required for the review of genomics research. This is because the review of genomics studies is challenging: the science is difficult to comprehend (Hoedemaekers 2006), the studies are hypothesis-generating rather than hypothesis-testing, use very large sample numbers (Cardon 2001; Donnelly 2008) and generate very large amounts of data that can be analysed many times for different purposes. (de Vries 2011). The ethical review system in Nigeria seems to mimic this opinion. Research Ethics Committees of categories C, D and E are not

allowed by NHREC to review genomics research, perhaps because they have not shown competence in this area.

Table 2.1: Categorization of Nigerian Health Research Ethics Committees. Adapted from, http:// http://www.nhrec.net/nhrec/hrec_db.php. 01/10/2011.

	Category-Colour Code	Authorization	Exclusions
	A	Authorized to review all types of research	None
	B	Authorized to review Phases II, III and IV clinical trials, vaccines and biological products trials, genetic, social and behavioural trials, alternative and complementary medicines and epidemiological studies. Also authorized to review trials in vulnerable populations	Novel products with potential nation-wide religious, social and security implications and research including use of radioactive pharmaceuticals should be referred to NHREC
	C	Authorized to review Phases III and IV clinical trials, social and behavioural trials, alternative and complementary medicines and epidemiological studies. Also authorized to review trials in vulnerable populations	In addition to exclusions for categories above, Phase I and II clinical trials, vaccines and biological research, genetic research
	D	Authorized to review Phases III and IV clinical trials, social and behavioural trials and epidemiological studies.	In addition to exclusions for categories above, complementary and alternative medicines research and research among vulnerable populations
	E	Authorized to review epidemiological and social and behavioural studies. No clinical trials authorization	In addition to exclusions for categories above, this committee is not allowed to review ANY clinical trial

2.7 Role of Material Transfer Agreements in preventing community harms:

In a review of perspectives and challenges in identifying indigenous peoples for health research in a global context, authors concluded that while health researchers need to understand the indigenous peoples with whom they work, ultimately, indigenous groups themselves best define how they wish to be viewed and identified for research purposes. (Bartlett 2007). They also need to understand that the indigenous

groups reserve the right to determine how their samples will be collected, stored and utilized. It then follows that communities in developing countries should be provided the leeway to determine how best to engage in genomics research and to avert the harms that may arise therein. These concerns can be taken care of by the use of a Material Transfer Agreement (MTA) which is a contract between two parties involved in a research project that specifies exactly the nature of work that is to be done on research materials or samples given by one party to the other. It typically consists of specifications about the following elements: the materials to be transferred; the exact work to be done on the materials; the conditions of storage of the materials, including for instance details on building access and security; the people that are to work with the samples, typically the heads of research groups and all the members of their group; the duration of the collaboration; an agreement about data sharing and collaboration in analysis; and procedures for agreeing on any other work that is not covered in the current MTA. (de Vries 2011). A well-designed MTA can be used to mitigate potential community harms arising from genomic research especially if the documents provides for continued dialogue between the community and the researcher, even after the end of the research.

2.8 Community Advisory Committee (CAC):

The use of a Community Advisory Committee (CAC) as the primary vehicle for community participation is also recommended. (Emmett 2009). In mitigating dignitary harms through a community participatory approach, adequate caution need to be taken as there would be different socio-political contexts of harm reduction in developing countries. Religion could also act as a barrier or facilitator of harm reduction interventions. (Philbin 2008). Actually, applying a community-based participatory research (CBPR) paradigm in genetic research can help to improve

protections for human subjects and communities, build trust between investigators and community members, and enhance protocol development and implementation. (Resnik 2010). The CAC also serves an important purpose in the process of group consultation to identify and to realize the specific implications of benevolence, justice, and respect for individuals with respect to a particular project. (Hausman 2007). The CACs help researchers cultivate trust among the research communities prior to the initiation of research. Cultivating trust requires, communicating project goals to both communities and individuals, disclosing and discussing alterations in the initial purposes of a research project as they occur and obtaining secondary consent when proposing new uses of collected data and samples. (O'Niell 2009). Community harms should actually be anticipated, discussed upfront and mitigated throughout the period of the research and afterwards by adequate community engagement.

2.9 Typical Role of Ethics Committees:

In the review of the MalariaGEN study, some of the ethical issues in human genomics research in developing countries were discussed. The main points raised by the stakeholders concerned how to ensure that participants give valid (informed) consent; the justifications for the export of samples and specification of the procedures for sample return or destruction at the end of the project; ensuring the appropriate recognition of local investigators' contributions and capacity development; ensuring that genomic data will not be used to harm populations or countries; and ways of assigning benefits to the country or community that donated the samples. A particular challenge related to the fast increases in the number of genetic variants that can be reasonably genotyped for a project like MalariaGEN. MalariaGEN adopted two ways

of approaching the challenge of obtaining ethics review. First, it held a number of ethics workshops to which members of some of the ethics committees were also invited. In this way, MalariaGEN received some very important feedback about what were perceived to be the key ethical challenges by ethics committee members, which could in turn be integrated into project policies and proposals. Second, when the Network was seeking to address particular issues, such as data sharing, it sought to establish working relationships with ethics committees to receive feedback on proposed policies. This enriched the Network's thinking about particular ethical challenges relating to the MalariaGEN studies. (de Vries 2011). These issues show that genomics is a fast-moving field in which new technological opportunities are developed monthly. These opportunities ought to be exploited to maximise the benefits of genomics studies but the implication is that for several studies, the ethics approval would be outdated by the end of the study if not reviewed periodically. The MalariaGEN approach could be employed for genomics researches in other developing countries. International sponsors of genomics research and the researchers should engage the consultancy services of bioethicists well-knowledgeable about the communities in the developing countries that will be engaged in the research, even as early as the project conception and design.

In a recent study, up to 67.5% of survey respondents indicated that although they held positions in either Institutional Review Board (IRB) administration or regulatory/compliance functions, they were not familiar enough with the NIH GWAS data-sharing policy to hold or give an opinion about its usefulness. Most of the survey respondents believed that special guidance should be provided to researchers whose plans include developing a data repository or biobank that would include genetic data, secondary use of de-identified genetic data, or sharing their genetic research data with

other investigators. In their opinion, without clear regulatory guidance on these issues at the federal level, for instance, individual IRBs across a country would likely duplicate efforts in ethical review, dedicating a portion of limited resources to solve a shared problem. (Lemke 2011). This finding is a matter of some concern, particularly considering the fact that researchers and IRB members in developing countries could be far more unfamiliar with any or all of the existing global policies and regulatory frameworks in genomics research. There may not be equivalent regulations or guidance documents in most of these developing countries.

2.10 Confidentiality Certificates:

The issuing of confidentiality certificates to researchers can be used to avoid exploitation, stigmatization and discrimination against the research subjects or their communities by legally protecting the researchers from revealing the names or identifying characteristics of participants in their researchers even in the court of law. This practice started as an initiative of the National Institutes of Health (NIH) whereby researchers may obtain certificates of confidentiality for research on sensitive topics, whether the research is funded by NIH or another agency. Qualifying studies for the issuance of confidentiality certificates include those that collect data on such topics as sexual attitudes, preferences or practices; use of alcohol, drugs, or other addictive products; mental health; genetic makeup; illegal conduct; or other topics for which the release of identifiable information might damage an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination. At present, however, the protection afforded by such certificates is prospective. This means that, researchers cannot obtain protection for study results after data collection has been completed, and it is not always obvious in advance when a certificate maybe needed. (Constance 2003). Considering the

globalization of research and the international scope of genomics research with most of the funding from the NIH, it is recommended that the use of such confidentiality certificates should be employed in Nigeria.

2.11 Ethical, Legal and Social Issues (ELSI) and Frameworks:

There is a real concern of whether appropriate legal frameworks exist to address the issue of community harms associated with research especially in developing countries. Few studies have been done within Nigeria to address social issues surrounding genetic research. A study on voluntary participation and informed consent to international genetic research done simultaneously in USA and Nigeria revealed that fewer than half of the respondents at both sites reported that the study purpose was to learn about genetic inheritance of hypertension. Most respondents indicated that their participation was voluntary. In the United States, 97% reported that they could withdraw, compared with 67% in Nigeria. In Nigeria, nearly half the married women reported asking permission from husbands to enrol in the hypertension study; no respondents sought permission from local elders to participate in the study. The findings highlight the need for more effective approaches and interventions to improve comprehension of consent for genetic research among ethnically and linguistically diverse populations in all settings. (Marshal et al. 2006). The key ethical, legal and social issues (ELSI) in longitudinal, genetic research studies involving children, for instance include: (1) recruitment; especially the scope of parental authority to permit a child to participate in research; (2) the nature of consent sought, particularly the breadth or specificity of initial consent, and subsequent seeking of assent and/ or consent from the child; (3) confidentiality and sample/ data protection measures; (4) handling sensitive information (e.g. signs of child abuse); (5) disclosure of results to participants; and (6) withdrawal from the cohort. (Ries et al. 2010).

CHAPTER THREE

RESEARCH DESIGN AND METHODOLOGY

3.1 Methods/Study Design:

This descriptive study involved the use of using Key Informant Interviews (KIIs), In-depth Interviews (IDIs) and Focus Group Discussions (FDGs). The collection of the qualitative data from the study population was done using a 'Purposive Sampling' and snowball sampling method, (Capron et al. 2009). We conducted five (5) FGDs, involving about 8-15 persons in each group. 3 of these groups were made up of only men. Two of the remaining groups were for women, but for the second women group, 6 women were joined by 3 men, as a condition for their participation. (Table 3.1) For the KIIs, 9 persons including a woman were interviewed in Igbo-ora, and for the IDIs, 6 persons (not resident in Igbo-ora) but previously or currently involved in ethical review of research conduct were interviewed. The final number of interviewees and participants was determined by extent of information collected in accordance to the snowball method. Sampling was completed within three (3) weeks of commencement of the field survey. The data was analyzed manually using modified thematic analysis. In the Key-Informant-Interviews, and In-Depth Interviews, open-ended questions, and a semi-directive style with a few structured questions was utilized; in particular the respondents were prompted to explain the basis of their conclusions. The date was recorded electronically and partly in writing, later transcribed and analyzed. Prior verbal consent were sought and obtained from each participant (individually or collectively) orally after proper consenting. Acceptance to participate in the study and the permission for the audio recording of the participants' comments and opinion were considered a valid consent. Separate guidelines were used for the KIIs, IDIs and FGDs but all the three sampling methods addressed overlapping thematic areas. The FGD and KII guides were translated and interpreted to the Yoruba language for the uneducated members of the community. (see Appendix- 1, 2 and 3).

Table 3.1: Survey Respondents' Characteristics.

FGDs: Igbo-ora People.	**Group 1- Men** 15 men aged 28-65 years. 4 artisans and 11 farmers. **Group 2- Men** 13 men; 1 aged above 55 years; others 30 to 45 years. 2 artisans, 8 farmers, 3 petty traders. **Group 3- Men** 7 men; 30-45 years old; Farmers.	**Group 1- Women** 10 women aged 25 to 45 years. 6 nursing mothers and 4 other housewives, two of whom work in a health facility. **Group 2- Women** 6 women (5 aged between 25 to 45 years; 1 above 45 years); all are housewives/farmers. 3 men (less than 50 years); had to join because the women insisted they may only talk if their husbands are around.	
KIIs: Igbo-ora Community leaders.	2 School Principals, one of whom was involved in mobilizing the community for two concluded research projects; 2 Religious leaders (Christian and Moslem); 1 community leader known for directing researchers in community engagement; 1 technocrat/bureaucrat who has been involved in mobilizing the community for research; 1 legal practitioner indigenous to and living in Igbo-ora; 1 elderly traditional ruler who sits in council with the Kabiyesi; 1 female community leader who works in a health facility.	**IDIs: Bioethicists and REC members.**	6 Bioethicists; 4 of who currently sits on a Research Ethics Committee review meeting. The other 2 also sat on REC meeting in the past.

3.2 Research Setting:

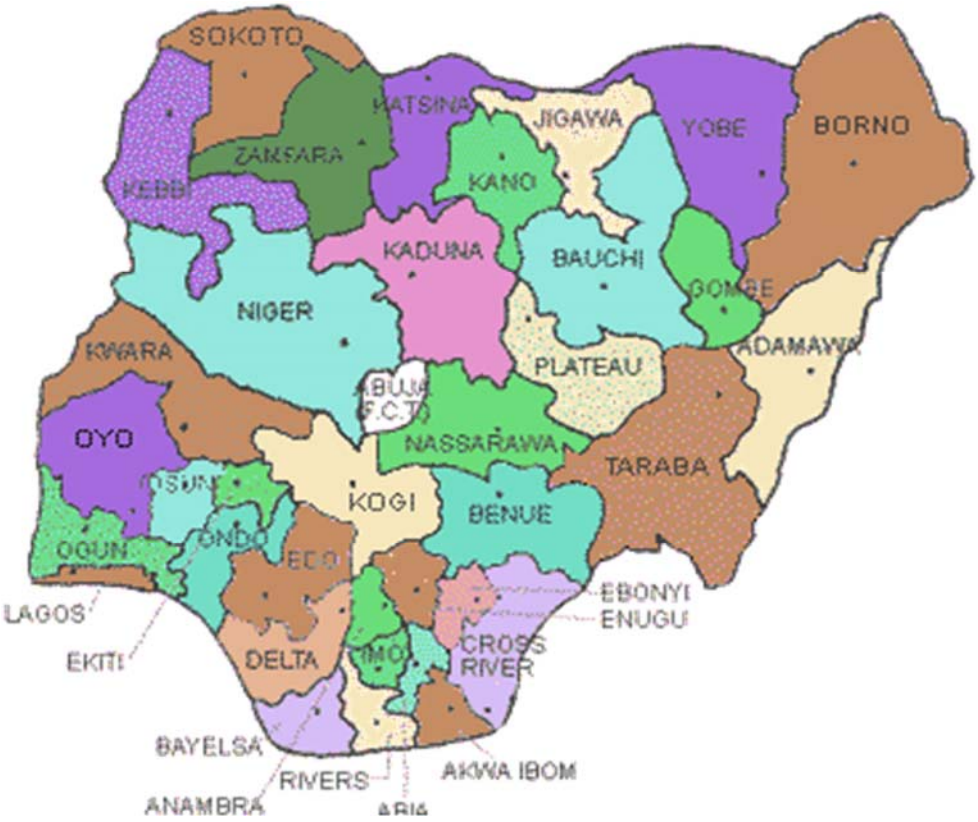

Fig 3.1 : Map of Nigeria showing Oyo State; the Study Area.

Source: http://www.waado.org/nigerdelta/Maps/Nigeria_States.html

The study was conducted in Igbo-ora community in Oyo State, Nigeria. Igbo-ora is the headquarters of Ibarapa central LGA in Oyo State. The community has an estimated population of 66,612 (NPC, 1991). The Ibarapa central LGA was carved out of the former Ibarapa district. The great Ibarapaland is made up of three LGAs including Ibarapa East, Central and North. Oral history indicated that people came to the present Igbo-ora community from the traditional Ekiti (in Ekiti State), Egba (a group of communities in Ogun State), Iberekodo (a small community in Abeokuta, Ogun State) and Oyo (a traditional town whose name was taken after to name Oyo State). Hence intermarriage over time brought them together as a community.

Igbo-ora is situated on longitude 71° 2' N and latitude 30° 4' E (Watson & Wareham 1963). It is about 100km west of Ibadan, the Oyo State capital and about 40km northwest of Abeokuta, the Ogun State capital. The people of Igbo-ora are predominantly Yoruba and the settlement according to Adebayo (1996) is made up of 339 extended family housing clusters called compounds or "*agbole*". Igbo-ora people are predominantly farmers and agriculture is the mainstay of the local economy. The crops commonly grown there include cassava, yam, melon, and maize. There is a small population of ethnic minorities in Igbo-ora. They are the Fulani nomads who came from the Sahel and Savannah regions of West Africa and migrant farm labourers from the middle belt of Nigeria, and nationals from Togo and the republic of Benin (Oyadoke, Brieger, Adesope and Salami, 2003-2004.).

Generally, the Onko, a Yoruba dialect is the main language of communication in Igbo-ora. Majority of the people are Muslims and Christians, with few adherents of traditional African Religion. It is common to find people who combine the practice of either Christianity or Islamic faith with the practice of traditional African religion. While men are critically involved in clearing, cultivation and planting of crops in the farm, the women engage in the processing of the farm produce. Many women are also engaged in trading activities. A few people are civil servants and artisans. Most civil servants and artisans also farm to supplement their family food income and food supplies. The extended family system is a cherished value in Igbo-ora. Extended family members often live in clusters of dwelling units called compounds. In Igbo-ora, a compound usually consists of several dwelling units with households who share a patrilineal relationship.

The community is divided into six blocks (Oke-Iserin, Isale-Oba, Oke-Odo, Idofin-Saganun, Pako-Pembo, and Igbole-Iberekodo) with a total of 63 Enumeration Areas

(EAs). Each building in the blocks has an assigned number which facilitates demographic activities including birth registrations at the General Hospital (Ayeni & Olayinka 1979). There are 20 primary schools, 8 secondary schools and the Oyo State School of Agriculture, in the town. The General Hospital is jointly run by the College of Medicine, University of Ibadan and the Oyo State Government. Three local government maternity centres and dispensaries, and four private clinics exist in the community. Patent medicine vendors are found in the community (Oshiname & Brieger 1992) from whom residents buy drugs for the management of simple ailments. There are few herbalists in the community. Igbo-ora has four markets located in different parts of the community. The markets hold on different days usually on a five-day rotational basis.

The study involved sampling of data from members of the Igbo-ora community who could be potential or actual genomics research participants. Bioethicists and Ethics Committees members who review human subject research within Oyo state (whether in Igbo-ora) or elsewhere, were also be sampled in this study. Igbo-ora was chosen for this study because of the participation of this community in many medical researches including genomics studies. Members of the ethics committees and the researchers who participated in this research did so anonymously and not in their official capacities as ethics committees members.

3.3 The Study Population:

These comprised of (1) male and female adult members of the Igbo-*o*ra community; (2) community (religious/traditional) leaders and government officials who may be charged with responding to group harms in the community, should they occur. (3) Bioethicists and ethics committee members who review research protocol in Oyo State.

The research participants for the Focus Group Discussions were approached and recruited through the assistance of a community-based research support volunteer. Key Informant Interviews (KIIs) were used for the community leaders while In-depth Interviews (IDIs) was employed to sample information from the Bioethicists and Ethics Committee members. Valid informed consent was obtained at the beginning of each session and documented by means of audio/voice recording.

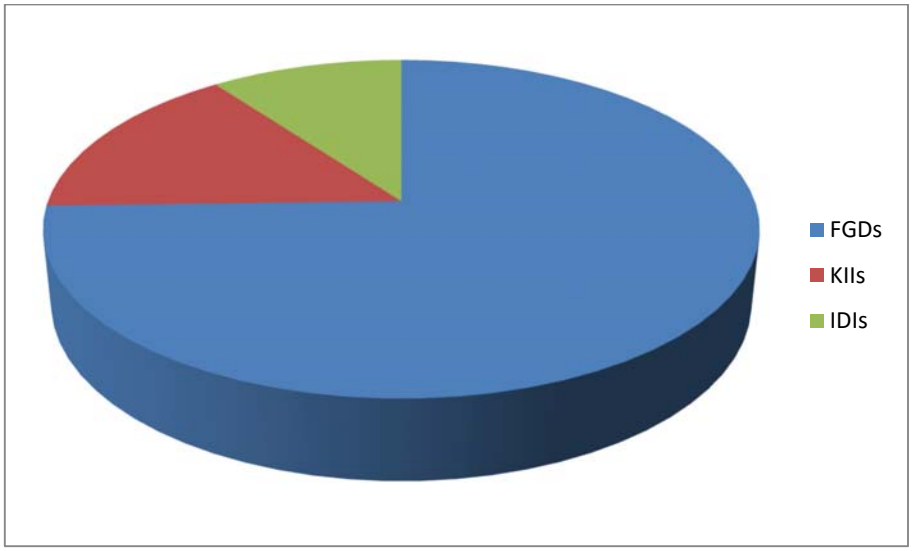

Fig 3.2: Pie chart showing distribution of respondents.

3.4 Potential Risks:

This study was a minimal-risk study as no identifiers were used or involved in dealing with the participants. Nevertheless, subtle psychological risks may as well be related to the nature of questions used in the study. Measures were taken to avoid any breach of confidentiality and to preclude exposure of the study materials and results to unconcerned persons. Ultimately, the advice of the ethical review committee was embraced in protecting the study participants.

3.5 Justice and Fairness:

The decision to conduct this study in Nigeria is justified, considering that our country is a very prominent developing nation with huge naïve black population, and a rapidly-evolving genomic research capacity. There has also been no such study conducted in-country.

3.6 Legal responsibility/litigation:

The sample collection procedure for this research was hitch-free. Litigations are not expected to rise from the procedure and henceforth, as the appropriate ethical and regulatory frameworks were adhered to. Participants' confidentiality was not breached as there were no identifiers used in the study. As the researcher, I shall indemnify any participant for any damage or loss incurred in the process of participation in the study within the limits of approval by the ethics committee.

3.7 Method of Data Analysis

The audio recordings of all the interviews were transcribed, verified, and analyzed by the author. The analysis was done thematically, in accordance with the outline used for the FDGs, KIIs and IDIs.

3.8 Dissemination of Result of Study:

The outcome of this study has been presented (as a poster) at the Ethics and Genomics Research in Africa (EAGER) conference of November 28-29th, 2011 in Abuja Nigeria. It shall also be presented to the University of Ibadan project defense committee before it is finally submitted in partial fulfilment of the requirements for the MSc degree. The research finding shall also be communicated to the ethics committees that reviewed the proposal after the defense of the dissertation; this was one of the specific requirements. Abstracts from the work shall also be submitted to other relevant local/international

scientific conferences. There shall also be article publications in peer-reviewed international journals.

3.9 Limitation of the study:

This study is conceptualized to address community harms in genomic research in developing countries but is limited to a state in Nigeria. The findings of this study though expectedly typical of what would be obtained in other sub-Saharan African countries may not entirely represent the situation in all developing countries.

3.10 Ethical Considerations:

The ethical approval of this study was granted by the Oyo State Research Ethical Committee. This study was conducted in accordance with the stipulation of the Nigerian National Code for Health Research Ethics, and other relevant international guidelines. Informed verbal consent was obtained from the study participants before conducting the interviews and discussions. The consent process was audio-taped for record purposes. The discussions and interviews were conducted in settings that ensured respect to the dignity and privacy of the participants; the participants themselves determined the places used for the interview.

CHAPTER FOUR

RESULTS

4.1 Demographic characteristics of the FGD respondents.

The FGD respondents comprise of adult men and women. The first was a group of 15 men aged 28-65 years. There were 4 artisans and 11 farmers in this group, and all were resident in Igbo-ora. The second group had 13 men; 12 were between 30 to 45 years but one was above 55 years. Among them were 2 artisans, 8 farmers and 3 petty traders. 7 men aged 30-45 years made up the third group who said they were all farmers. The first group of women had 10 members aged 25-45 years; 6 nursing mothers and 4 other housewives, two of whom work in a health facility. This group were interviewed after their visit to a health facility. The second group of women had 6 women (5 aged between 25 to 45 years; 1 above 45 years); all were housewives/farmers. 3 men (less than 50 years); had to join the group because the women insisted they may only talk if their husbands were around.

4.2 Demographic characteristics of the KII respondents.

The KII respondents were 2 School Principals, indigenous to Igbo-ora, one of whom was involved in mobilizing the community for two concluded research projects; 2 Religious leaders (Christian and Moslem); 1 community leader known for directing researchers in community engagement; 1 technocrat/bureaucrat who has been involved in mobilizing the community for research; 1 legal practitioner; 1 elderly traditional ruler who sits in council with the Kabiyesi; a health worker in the and a female community leader who also works in a health facility.

4.3 Demographic characteristics of the IDI respondents.

The 6 Bioethicists that participated in this survey where all males; aged 40 years and above were all engaged as academic staff in universities. 4 of them currently sit on a

research ethics committee review meeting. The other 2 also sat on RECs in the recent past.

The findings of the study fall into several themes that emanated from the responses of the study participants.

4.4. Awareness, perception and participation in genomics and other researches:

4.4.1 FGDs and KIIs

The people of Igbo-ora were not aware of genomics research and say they had not participated in such before. However, they had ample experience with other forms of medical research. This is revealed by the consistent responses obtained about this in the FGDs and KIIs. The community dwellers had participated in a research, in which farmers were asked about how they get, save and use money. Others participated in Malaria, Guineaworm, Onchocerciasis, Yellow fever and Hypertension researches. According to one FGD respondent, people came to the community, moving round the villages and checking people's blood pressure. Anyone that had high blood pressure was referred to the hospital. A female FGD respondent had participated in a research but "…not in the hospital, in school; they just came to test our blood samples". They were not given any explanations for the research and did not get any results or feedback from the researchers. Nevertheless they did not feel bad or annoyed because the school administration instructed them to participate in the research. While most of the KII respondents think there was no on-going research in Igbo-ora at the time of the study, a male respondent said he was aware of several researches "…one of which is the Malaria research project which is even on-going". Another respondent said, "I was part of the research team in Sekere, Geke and Semi." But said there was no on-going research in Igbo-ora.

Concerning the opinion that there was no on-going research at Igbo-ora at the time of the study, the participants had no reason why this was so but one of the IDI respondents who sits on an ethics committee opined that there was a decision among the university research community to reduce research approvals for the community, in view of the very many research projects approved for the community in recent years.

Generally, the respondents of the FGDs and KIIs were disposed to participation in research of any kind. We are happy with research, they said. We got benefits like potable water; overhead tanks, hand pumps and boreholes from the Guineaworm research. One KII respondent, who mentioned he came from a legal background, maintained that in Igbo-ora, researchers will not have problems about harms because research is seen as humanitarian. However, in the second FGD, some women revealed some dissenting opinions. The female participants who *ab initio* insisted they would only participate in our survey with the presence of a few of their husbands said that "whatever we do as women, we get permission from our husbands. We were reluctant to participate even in this your research because we have not seen the benefits of previous researches". We will not feel happy to give our samples because we are not clear with what they will be used for. Researchers do not tell us about benefits.

In response to the question whether any category of people are exempted from research in Igbo-ora, the FGD and KII said no body is exempted from research. Anybody can participate in research; research is good for us and has benefited us. If we see there is no harm in the research, we will allow everybody to participate. Our people will receive genomics study because convulsion reduced in our place because of research. I believe researchers cannot harm or injure us, or the Igbo-ora people. They have our benefits in mind. While discussing the Guineaworm research, one respondent (KII) said: "In this community, through our participation in many researches,…we have benefited a lot;

so as a community leader, I can confess on that…when the people, the officers in charge of Guineaworm have been coming, they give us orientation, they educate us, they tell us the right things, ..so that is a good impression as a community…anybody that is now coming for research,..we will be able to tell our people to participate because they come here to help us."

4.4.2 IDIs

Most of the IDI respondents think that there was very few ongoing genomics research in the study area at the time of sampling. One dissenting voice thinks otherwise. According to him, "….actually the experience is not low at all…. I would not say the experience (about genomics research) is rare, low, or anything."

With respect to participation, only one person was involved in genomics study. In his words, "I have been actively involved in genomics research and ethics. I have reviewed several protocols that have something to do with genomics research especially in cancer research".

Another respondent said, " yes in terms of reviewing protocols; our centre has been involved in genomics studies; one study was done by Prof Clement Adebamowo and his team many years ago".

There was no knowledge about community harms in Nigeria, among the respondents of the IDI; "maybe because we do not have adequate information", a respondent replied.

4.4.3 Sensitivity of genomics research:

All the respondents agree that genomics research is more sensitive than other human subject researches. Common responses include: yes; this kind of research is more

sensitive. Conflicts between ruling houses can occur because of such studies. Our people may be concerned about studies which may contradict beliefs about lineages because such findings can affect ascension to kingship or other positions in the community; one ruling house may use such research findings against another. Yoruba communities believe they have a common ancestry and may not welcome any findings challenging this.

In the words of one KII respondent, "Well, every research is sensitive; some are more sensitive than others". There are greater risks of harms to the community because of some discoveries in individuals, for instance the predisposition to mental disease or cancer. One IDI respondent said that genomics research is more sensitive because genes are involved; the findings of the study have implications not only for the individual but also for the relatives and family of the person. "As for risks which implies potential danger or potential harms, genomics issues have more than an individual implication and risks especially when you have access to a pool from an identifiable group". If the findings of a genomics research are negative, they would cause stigmatization. The outcome is of concern and how the data is managed is critical, in terms of publication especially with respect to the confidentiality of the subjects. With respect to the level of risks, an IDI respondent said that different types of genomics research have different levels of risks. In response to the issue of sensitivity, another IDI respondent also said "well it is all said, information is power, and when you have access to materials (DNA) from which you can extract sensitive information about a person …that shows how sensitive the research is……If somebody because he has the access to the materials goes to do other things ….the legality of the whole thing is suspect, you have to look at… what did you consent to..? If it is sensitive, therefore it must impose a higher duty even

where the consent has been obtained initially …….the consent is like a blank cheque…..”

The FGD respondents also explained that if blood is collected, without information on what it will be used for and where it will be taken to and the duration of the research, they will feel unhappy with that. This is because of our Yoruba culture; blood is sensitive and people have ben coming, and telling lies about what they use blood for, they said…“anything you take from somebody’s body as a sample is sensitive to that person.” If the research will bring good to our people, we will allow it to go on. Tests that diagnose things like Malaria and Typhoid (“Iba”) are acceptable by us, but if a deep test can make family unhappy, by revealing bad conditions like sickle cell, madness, cancer, that one is a problem, and is very sensitive. That is the main reason why illiterates do not like going for tests, because doctors tell them the whole outcome. So before even the disease in question starts, the person may have developed hypertension. “To prepare somebody’s mind about bad thing is not good”. Another FGD put it this way; this thing relates to HIV test. If you say somebody has HIV/AIDS, it will make people to stay away from him and put him into thinking and hypertension.

The IDI respondents (research ethics committee members) said that genomics research should be treated differently compared to non-genomics research. One respondent said that “(genomics research) imposes a higher duty on researchers”. It is also more sensitive because of the involvement of blood most times and because whatever is found in the genes has implication “not only for the individual… but also for the relatives and may be the entire community”. Notwithstanding, all the respondents (FGDs, KIIs, and IDIs) believe that the risks of injuries and harms in genomics research are not sufficient deterrent to individual or community participation in research.

4.4.4 Awareness about community harms in research:

All the survey respondents said they have not heard about problems with research in other communities within Nigeria. IDI respondents also do not have knowledge of community harms in Nigeria and think maybe because "we do not have adequate information." About instances abroad, one respondent said "the literature is replete with so many cases, when you talk about the US Tuskegee research … and the fact that …Clinton had to apologize for what the US did as a nation. But I think … such things too, you must not forget the fact that, often it is shrouded in secrecy, except when you now have some progressive scientists now coming out to say no, this must not continue. It is as if,.. if there is a conspiracy, then it may get unreported. Except the community will now come to say, we cannot allow this to come up. Because....before …. is community awareness…. there are so many, may be publications out there that members of the community that is affected, (they) are not aware of. It is after they are aware, that they will now begin to make an issue…. or maybe demand that there should be a retraction or an apology."

4.5 Concepts of harms in researches conducted in Igbo-ora:

4.5.1 FDGs and KIIs

The study participants, resident in the community conceptualized the harms they have suffered due to research variably. Although they said that no research was debasing to them as a community in the past, they reported that some people were offended about the use of abate chemical in water, in an attempt to kill the vectors of Guineaworm. "In Guineaworm research: abate chemicals added into ponds polluted water bodies and

killed many fishes; our people were offended. Some older villages felt dishonoured when researchers did not consult them and first dug boreholes for the newer villages in Igbo-ora." This could have been avoided with proper consultation. The decision to construct boreholes in different parts of the community was also not discussed with the elders and some villages felt insulted with the pattern of sitting the boreholes. Some participants of the Malaria Immunology researches were also said to be negatively affected; "some farmers developed whitlow". Some died and our people thought it was due to the infection, a respondent of the KII said.

In explaining what could amount to harm in research, a respondent said that no research had been debasing to them but that some researchers collected their samples and did not tell them what benefits we will get. The eldest respondent of the KII who was also illiterate lamented that people extort money from them by coming to diagnose diseases and asking them to pay to be treated. He said that some dribbled them; collected blood from people and did not give them any result. To him, he cannot tell who is a researcher, student, quack or fake doctor and for this he would not agree easily to engage in research.

4.5.2. IDIs

Physical harms, like pain in the process of sample collection; Psychological and Social harms were enumerated. In their opinion stigmatization is a psychological harm; "not giving feedback to communities is also a type of harm" according to two respondents. On this matter, another respondent who has been involved in community research as an investigator (and not privy to other respondents' views) said that feedback is actually demanded by communities but researchers fail to provide it. The issue of justice is also

important; why is the community selected for the research? If it is because of a wrong perception, that could be social harm. Not compensating the participants for their time and discomfort is also psychological harm. A research ethics committee member also said that not sharing findings of a research can be a form of exploitation. This is more likely to occur when there is lack of monitoring and evaluation of approved studies by research ethics committees. Another respondent said, "I think the principal problem is stigmatization. …so and from the legal perspective, stigmatization may now …. mature to discrimination. And of course, our constitution forbids discrimination on some grounds, because it compromises the idea of equality. And when people are stigmatized, it is like their dignity is assaulted. (Dignitary harm). And then, their ability to access some services may also be prejudiced. So that is a challenge especially when it relates to a group that is not particularly mobile, may be, who operate within a particular location. So if you are talking about a mobile group which is quite easily dispersed, then, the harm is not profound. But when you talk of a group you see, a community that you often locate within a particular geographical setting…the way the information will be passing here and there... …In this part of the country, …the way people pass that information at times to their children,… like I remember growing up…the Yorubas believe that wealth comes in trickles,… and that if there is a person they see is a sudden millionaire, sudden 'money bag'.. they warn everybody please don't go to his house, don't relate with him, because we cannot explain the source of his wealth. … so if they can apply that in a matter that has interest in economic foundation, …they can also extend the same thing like, 'don't go to their house,' on account of a particular ailment or disease which genomics research has come up with (revealed). - It could cause disaffection."

4.6 Concerns about participation in Genomics Research:

4.6.1 FGDs and KIIs

The respondents said they will participate in genomics researches, but if a research predicts a disease and it does not occur, people will say research gives wrong information and many will not want to participate next time. If a genomics test shows that some children in a family have the genes of their father while others do not, it will destabilize and disorganize the family. The man "…may not like the wife again, because she goes elsewhere to get a baby for me". If other people hear this, it will be a kind of disgrace for the father and entire family and will cause him depression. A test result that is alarming or showing that a disease can occur in the future can affect girls and men in a family in getting married. The community would basically discourage people from going to (marrying in) families that will have a health problem in the future. Such result can also affect the eligibility of a ruler to be chosen even within a ruling house. A test may bring happiness or unhappiness. In one FGD a respondent said that if research reveals a lineage of a ruler and shows he is not qualified to rule, he will become ineligible and the community will like it and remove him. If it happens to me, it has spoilt my career and I will go on self-banishment because people will look down on me.

In response to the question about their probable reaction, should it be, they were engaged in genomics research without being well pre-informed, they said; we will feel unhappy. Next time we will not allow another person to sample us, because we feel it is a betrayal. The community will not fight such researcher. Another respondent said that nothing special may happen; we may not abandon the research. Our people could write petitions against the study. Contrarily, two respondents said that they would take legal actions if their people are exploited in the process of research. A researcher had worked in our place and got results that were sensitive. The community would call such

persons to order. Moreover the IDI respondent with who has a legal background had this to say, "well I think there are different options open… we have administrative options: … since the people always constitute a local government, the local government can seek the administrative support of the state to demand more explanation and more so if the integrity of the finding or obtaining the samples is compromised, in terms of, if it is vitiated, the consent requirement is not observed, then they have a legitimate reason to stop the research. Then because the legal option is expensive …then some of these issues, they have not fully crystallized because of lack of precedents, then also because a lot has to do with the appreciation of all the issues by the judge. ….then, don't forget that we also know that we must not stifle research, we must encourage research. … so but to a judge atimes; if you are telling a judge who is not conversant with these issues.. genomics, you talk about harm to the community…the law will look at the remoteness ….if you are saying harm… you must be able to show that it is not just remotely connected. In which case there must be nexus, the connection must be direct… If it is rather remote, it is not likely that the legal option will come up (will assist), so but the main thing is that if we have a system where at the beginning of the research we are able to address the situation and that is to institute a community consent system so that informed and experienced people can look at the various protocols and then make appropriate recommendations; because the researchers too will expect to benefit from the product of the research. But this is just to tell us that all we that can have from the research is not benefit, we can also have problem".

In the opinion of the respondents, the Yorubas will be interested in genomics studies even if they are being used for the studies before other tribes are involved. Igbo-ora people like research and will like to be the first. Stigmatization is of concern if the research could reveal a tendency to early death or health problem. We need somebody

to guarantee that the research will not harm people especially if it is new. Will the researchers promise to tell us the results? Communication of the findings is a problem in our opinion. This should follow community's values, like the reporting and interpretation of the results like the soothsaying of the "Babalawos", they said. They had no particular concerns about research specimens. A respondent of the KII said that people will even like to give their urine and saliva/sputum samples easily because of the benefits of treatment which Diabetes and TB patients have enjoyed in research.

4.6.2. Other Concerns about harms in Genomics Research:

In response to the question about concerns when one's community/tribe alone is selected for genomics research include, an IDI respondent said he would ask about how his tribe was chosen...what the justification was and how the data would be used.

If genomics research is sponsored by a developed country in a developing county, the FGD and KII respondents had no particular concerns, but the IDI respondents have different views. Developing countries they said should be very critical of foreign researchers/sponsors, because of the lack of adequate institutional frameworks to validate their claims. "For us as developing countries, we must take the position of being very critical about what comes from abroad, because one, (maybe) we bear the brunt of stigmatization more, (especially when) given the background of slavery and all kinds of assault and violation of the right to the dignity of man, so there is a need for us to have institutional framework that can validate what they bring from abroad whether (it will) our own local circumstances will allow it. The damage is more here, once a family is stigmatized, unless they relocate to another community, because of our own social networks; so that family is affected. Some of these things are anchored on superstition and religious beliefs. People from abroad can easily get out of that

environment. The view…the consequences of stigmatization are not as indelible as when it comes to us. They can give scientific explanations and easily dismiss it. But here in Africa, once harm is done, the harm is perpetually done. Even for very useful research, we have to deal with cultural sentiments.. look at the polio research and the information that it can cause sterilization. You have to deal with that cultural mis-information."

According to one respondent, the revelation of susceptibility or predisposition to a disease following genomics research may only be seen to be positive if the solution can be discovered.

The concerns when genomics research challenges assumed/known paternity and ancestry was also re-echoed by an IDI respondent; the outcome being probable destabilization of the family.

An IDI respondent was also concerned about the implications of commercialization of genomics research findings; a situation where …. The issue of breaking the news and communication of the outcome of genomics research result was also raised by this person in view of the low level of awareness among healthcare workers. Result findings should follow traditional values in dissemination.

4.7 Mechanisms and frameworks to protect community members that may be engaged in Research:

All the respondents of the FDGs were not aware of any ethical, legal, or social framework or mechanisms that prevent or address community harms. We are not aware of what the government or hospitals do to protect people. Our community addresses problems with research as they occur based on individual and family decision. When

they see their people with unknown visitors or researchers, they caution them privately. They may take researchers and medical students to their Kabiyesi and Hospitals. Another respondent also replied about this issue thus; we do not know if government or anybody has any protections for people in research. Researchers come through bona fide persons who are enlightened to Igbo-ora. These enlightened persons provide protection for the researcher and people. The need to use enlightened person was also echoed by the eldest KII respondent who said, I am not enlightened. The enlightened people in the community should ask proper questions.

Two (2) respondents of the KIIs mentioned that obtaining ethical approval is one way of protecting the subjects. (We know, just like you did for this study that researchers should get letter from Ministry of Health). The opinion of one of the IDI respondents in describing the available legal frameworks is that, "…the grounds of discrimination which the law prohibits, (they) are quite narrow; on the basis of age, sex, ethnic origin, religious affinity. Even when it comes to mental conditions, the law does not remove some of most discrimination on that ground. I remember a few years ago when somebody suggested that psychiatric tests should be conducted for judicial nominees… because if you look at the ways some judges behave, you wonder if everything is actually ok. …..It is the reasonable man's test that the law often adopts to solve so many issues…..If you look at the right to religious liberty, one can believe anything, but you cannot manifest all beliefs, I may believe that human sacrifice is good but I can't manifest it. If I attempt to manifest it I will be violating some other laws. But I may just believe that drinking blood is good but I can't go ahead…..but…..if you have progressive judicial thinking, the grounds of discrimination can progressively be enlarged, especially when you now proceed from the angle of dignity. So that to do this

is wrong, to do this is a violation of the right to human dignity; because the whole idea of ethics is about dignity."

Recommendations on the prevention and mitigation of community harms were proffered by all the respondents (FGDs, KIIs and IDIs). These include the researchers' use of guarantors in engaging the community for novel and risky researches, the use of community advisory committees in execution of genomics research project, adequate consultation with the community leadership before the publication of any potentially stigmatizing research finding, and more capacity building for REC review of genomics research. One KII respondent also advocated the establishment of a community research liaison office/centre in Igbo-ora to promote research subject protections and documentation of research-related events.

The researchers should expand their work to all quarters of the town. People should be told the reasons why the place was chosen and the opportunities (benefits) in the research. The researcher should use eligible people in all the parts of the town. Results should be kept secret.

4.8 Mitigation of Community Harms and Recommendations from survey participants:

Both the community dwellers (FGD and KII respondents) and the Bioethicists/Ethics committee members (IDI respondents) had recommendations on the mitigation of harms from research. It was suggested that no research without the approval of Igbo-ora enlightened people should be carried out. (There was however no specific forum or formal body of these enlightened people involved in research protections in Igbo-ora). To avoid the potential harm of stigmatizing results, community respondents suggested that the Obas, rulers and enlightened people should be consulted before sensitive

research findings are published. Any ridiculous research or study that will make people unhappy should be avoided. Sensitive results that could ridicule the community, should not be published by researchers unless after due consultation with the enlightened community leaders, they said.

The IDI respondents were also vocal in advocating proper community engagement; and the imbibing the tenets of "dialogue ethics" in dealing with the communities. There should be remediation when harms occur and researchers should be made to understand that they are under tortuous liability to protect the research subjects. The role and use of Community Advisory Committees were recommended with good explanation and interpretation of the processes of the research required *ab initio.* The disclosure of sensitive results should be in a culturally-tolerable way. It was also recommended that the NHREC Guidelines and code should be followed in conducting genomics research. Suggestions were also given on the way to review genomics research "… first we have to think of the available personnel, competent personnel in this field, so that we do not spread ourselves thinly on the ground … I think that genomics research is a proper case for maybe the National health research ethics committee to handle….so if we push it at that level, the committee will be able to assemble competent experts to address the issue.

In Nigeria of today, we have challenges of migrant population; it can be a reason to discriminate against such members of the community when it comes to allocation of political appointments ….That is the reason I said earlier on, that will not matter in the US. … (We have enough of such tribal conflicts; we shouldn't find a new way of compounding the problem). I think we can raise the capacity of the present Ethics Committees; and in sensitive cases, a matter they cannot handle; they can push them NHREC to handle."

4.9 Other concerns and expectations:

No researcher except you has asked about injuries or harms due to research in Igbo-ora. This community is known for research in Nigeria and all-over the world. The Government should build a research centre/office for us in Igbo-ora so that records of research and discoveries like these will be kept in Igbo-ora. These were the parting remarks of the KII respondent who said he has be involved with so many research projects in Igbo-ora even as a member of the team for some of the studies.

Another participant in the second FGD also asked what the cause of madness occurring in families where there was no madness before was. Moreover some participants of the FGDs (in a bid that proved their interest in and expectation of research benefits) asked us what we have for them for engaging them in the survey.

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATION.

5.1 DISCUSSION

5.1.1. Awareness and Participation in Genomics and other Researches:

Community dwellers have engaged in several research projects. There is a general disposition to participate in health researches including genomics research. Their experience with research and its benefits to their community informs this opinion.

They lacked an awareness of prior or current engagement in genomics research. This is surprising, and may be due to focus on the health related themes of the research rather than the genomics part. For example in a genomics of hypertension research, community members may focus on the hypertension. They believe that if the terms are properly explained, they are willing to participate in genomics research.

In one of the FGDs, the women refused to participate until the husbands joined the survey. This confirmed what Marshal et al (2006) observed during their study on hypertension; a study that took place in the same region of Oyo state, Nigeria.

Surprisingly the Igbo-ora community has suffered various harms as a result of medical research. These instances represent all the forms of harms (physical, psychological, social, economic, and dignitary,) apart from legal.

5.1.2. Concerns about harms and injuries in Genomics Research:

This study shows that the people of Igbo-ora appreciate the fact that community harms may arise from genomics research. There could be "unappreciated risk of intangible harm, even if not physically injured." (Saver 2006). Imagine how some communities got offended with the decision taken after a research about sitting of boreholes.

According to Lurie, (1997), residents of impoverished, postcolonial countries, the majority of whom are people of colour, must be protected from potential exploitation in research. Otherwise, the abominable state of health care in these countries can be used to justify studies that could never pass ethical muster in the sponsoring country. He went ahead to list the probable causes of vulnerability of developing countries communities to harms as poverty, low literacy rates, general poor health indices, and myriads of political, tribal and communal conflicts. The respondents in this survey demonstrated (from their responses) that illiteracy and potential for communal conflicts are more likely causes of predisposition and vulnerability to harms from genomics research in Igbo-ora. Their statements like, "if a deep test can make family unhappy, …that one is a problem, … very sensitive; that is the main reason why illiterates do not like going for tests,…" and "conflicts between ruling houses can occur because of such studies" confirm this.

The respondents were very concerned about the potential harms in genomics research, which they conceptualized as assault on one's dignity, injury, neglect, offence, poisoning and provocation, endangering life, deception, insult, extortion, communal conflicts, defamation, destabilization of families, disgrace, dishonour, discrimination, exploitation, and stigmatization. So it would not be out of place to say that Igbo-ora community's ample experience with health research is fraught with many cases of individual and group harms which border on physical, psychological, socio-economic injuries and emotional harms.

The concern about exploitation as elicited from this study is similar to what Annas and Grodin reported in 1998 when they opined that the central issue in doing research with impoverished populations is exploitation (Annas 1998), and that developed countries may simply exploit people in the developing countries by gaining knowledge from them for the benefit of the western societies.

In agreement with Hawkins (2008), this study also documented the vague and unclear meaning of exploitation. The respondents of the focus group discussions had remarked that not giving them the results of researches conducted in their community is a kind of deception, whereas a respondent of the IDI maintained that not giving feedback to the community is actually a form of exploitation. These two descriptions (deception and exploitation) represent the same form of social harm, although the conception of the FGD respondents portrays the harm as psychological as well. The expectation to provide periodic feedback is in agreement with the Nigeria code for health research. According to NHREC (2006), "it may also be necessary to inform the community from time to time about the progress of the research, pertinent findings that may influence their health and wellbeing, and, the outcome of the research."

The perceptions of harms as revealed in this study reflect the opinions of the survey respondents, and may not represent the formal position of the community. This is obvious for example, from the type of harms which resulted from the malaria and hypertension researches. These responses (about the physical injury which led to cases of whitlow and the cases of complications of hypertension among research subjects) were elicited from the two respondents of the KIIs but there were no specific instance of harm reported from the FGDs. The people did not have concerns related to the consenting process, perhaps due to the reduced influence of individualism on the society. Once the leaders, family heads and enlightened people are consulted, and they inform the villagers, adequate consenting is considered done. This is also the understanding for the recommendation of guarantors who are expected to come from the community, when the research is novel. To the respondents, harm due to genomics research is more likely to result mainly from the way the outcome of research is communicated. Dishonour, disgrace, and assault on one's dignity are serious when lineages and family histories are altered or challenged by the outcome of research.

5.1.3. Protection mechanisms for Communities and Mitigation of Harms:

The FGD respondents did not know about ethical/legal mechanisms for research participants' protection. Most respondents made reference to the need to use enlightened people in research, a method they suggested as a functional means of community consultation. Consultation is method of involving communities in research development and approval, in response to the traditional emphasis on the rights, interests, and well-being of individual research subjects. (Dickert & Sugarman 2005).

5.1.4. Mitigation of Community Harms.

This study shows that genomics researchers have to be culturally sensitive in places like Oyo State. Just like the Havasupai Tribe in Arizona in USA (Lowenberg 2010), the people of Igbo-ora attach a lot of significance to blood for instance. They however did not describe any spiritual or religious implication of this and also said that other types of body samples are considered as important as blood. According to them, this is because of our Yoruba culture; blood is sensitive and people have being coming, and telling lies about what they use blood for…"anything you take from somebody's body as a sample is sensitive to that person."

Getting informed consent is important to the Igbo-ora people but it is not in the context of the traditional ethical principle of individual autonomy.

The Igbo-ora community showed interest in the publication of the findings research done in their place. This is in agreement with the observation of Resnik and Keneddy (2010) that community partners often have specific interests related to the outcome of research. First, though most communities have an interest in publishing research about the community, they also have an interest in protecting the community from adverse publicity, stigma, discrimination, and other harms that could result from the publication of findings that report medical or social problems in the community, such as HIV/AIDS, alcoholism, prostitution, cancer, genetic diseases etc. The respondents' actual interest in publication is not just to share the credit but to ensure that the community and individual participants of the research are not harmed. Their opinion is that any research findings that have the potential of causing harm must not be published unless the approval of their village rulership is obtained.

5.2 CONCLUSION:

Communities in Developing Countries like Igbo-ora may be at risk of varied community harms due to genomics research. There is need for utmost cultural sensitivity and responsiveness in designing and conducting genomics research. There also a need to get people well-informed on the ethical, legal and social frameworks available to protect individuals and communities in research.

5.3 RECOMMENDATION:

A good paradigm for genomics research in developing countries; should entail a robust community consultation and dialogue mechanism. The survey participants made two key requests themselves; that researchers and government should think about setting up a research centre for them and also sought to understand the causes of some embarrassing illnesses like mental diseases. In our opinion, these and other issues can be addressed in the short and long-run if the idea of CBPR is imbibed and promoted in the area. We recommend that this study should be conducted in other parts of Nigeria and in countries of Africa among indigenous populations. Research funders should consider putting more resources in this area of empirical research. For proper review of genomics research protocols, adequate capacity building is required, and should be provided for the Research Ethics Committees.

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Table 4.1: Summary of the Focus Group Discussion Participants' views about community harms in genomics research in Igbo-ora and other developing countries.

Domains	Responses	
	Common responses	**Less Common Responses**
❖ Prior or current participation in research. ❖ Have you ever felt that your community has been wronged or injured in the process of participating in any research? ❖ Any knowledge of community harm or injury in a research? ❖ Are there people, your family or community would not want to be involved in research? ❖ Are there types of body samples or fluids your people may not give for research? Do you consider any sample more sensitive than others?	Yes. We have participated in a research were farmers were asked about how they get and use money. Others participated in Malaria, Guineaworm, Onchocerciasis, Yellow fever and Hypertension, Research. Many doctors came and moved round the villages, No ongoing research now. We are happy with research. No; no complain, no dishonour in research. Initially we did not know what will happen, but at the end, we benefitted from the researches. No None; anybody can participate in research; research is good for us and has benefited us. If we see there is no harm in the research, we will allow everybody to participate. No. If blood is collected, without information on what it will be used for and where it will be taken to and the length of research, we will feel unhappy with that. This is because of our Yoruba culture; blood is sensitive and people have being coming, and telling lies about what they use blood for. "Anything you take from somebody's body as a sample is sensitive to that person."	"…not in the hospital, in school; they just came to test our blood samples". People came to the community doing research about blood pressure. Any one that had high blood pressure was referred to the hospital. We got benefits like potable water; overhead tanks, hand pumps and boreholes from the Guineaworm research. Whatever we do as women, we get permission from our husbands. We were reluctant to participate even in this your research because we have not seen the benefits of previous researches. We will not feel happy to give our samples because we are not clear with they will be used for. Researchers do not tell us about benefits.

Table 4.1-contd.: Summary of the Focus Group Discussion Participants' views about community harms in genomics research in Igbo-ora and other developing countries.

Domains	Responses	
	Common responses	Less Common Responses
❖ Would you accept to be part of genomics research (studies about blood lineage, relatedness, disease susceptibility, ancestry, race etc.)	We will participate but if a research predicts a disease and it does not occur, people will say research gives wrong information and many will not want to participate next time. If a genomics test shows that some children in a family have the genes of their father while others do not, it will destabilize and disorganize the family. The man "…may not like the wife again, because she goes elsewhere to get a baby for me". If other people hear this, it will be a kind of disgrace for the father and entire family and will cause him depression.	If research reveals a lineage of a ruler and shows he is not qualified to rule, he will become ineligible and the community will like it and remove him. If it happens to me, it has spoilt my career and I will go on self-banishment because people will look down on me.
❖ If you did not know that a research has genomics components before participating in such a research, how would you react if you discover later?	We will feel unhappy. Next time we will not allow another person to sample us, because we feel it is a betrayal. The community will not fight such researcher. A researcher had worked in our place and got results that were sensitive. The community will call the person to order.	
❖ Assuming a research reveals disease susceptibility or challenges your ancestry, what do you think about that? If such a study is published without the knowledge of your community, how would people respond to that?	A test result that is alarming or showing that a disease can occur in the future can affect girls and men in a family in getting married. The community would basically discourage people from going to (marrying in) families that will have a health problem in the future. Such result can also affect the eligibility of a ruler to be chosen even within a ruling house. A test may bring happiness or unhappiness.	This thing relates to HIV test. If you say somebody has HIV/AIDS, it will make people to stay away from him and put him into thinking and hypertension.

Table 4.1-contd.: Summary of the Focus Group Discussion Participants' views about community harms in genomics research in Igbo-ora and other developing countries.

Domains	Responses	
	Common responses	Less Common Responses
❖ If a study is about genomics, are there any concerns you may have about participating in the study or allowing the study to be done in your community?	If the research will bring good to our people, we will allow it to go on. Tests that diagnose things like Malaria and Typhoid ("Iba") are acceptable by us, but if a deep test can make family unhappy, by revealing bad conditions like sickle cell, madness, cancer, that one is a problem, and is very sensitive. That is the main reason why illiterates do not like going for tests, because doctors tell them the whole outcome. So before even the disease in question starts, the person may have developed hypertension. "To prepare somebody's mind about bad thing is not good".	-
❖ Have you ever felt that a particular research was debasing or harmful to you or your community?	No; research is not debasing to us but some researchers collected our samples and did not tell us what benefits we will get.	-
❖ Have you ever heard of any group of people that were negatively affected by genomics research?	No	-
❖ What do your community, health centres, hospitals and the government do to protect people involved in research against harms?	We do not know if government or anybody has any protections for people in research. Researchers come through bona fide persons to Igbo-ora. These enlightened persons provide protection for the researcher and people.	
❖ What should be done to avoid problems when carrying out genomics research?	The researcher should expand his work to all quarters of the town. People should be told the reasons why the place was chosen and the opportunities (benefits) in the research. The researcher should use eligible people in all the parts of the town. Results should be kept secret.	
❖ Do you have any other concerns in your community about health research?	What is the cause of madness occurring in a family where there was no madness before?	

Table 4.2: Summary of the Key Informant Interview Participants' views about community harms in genomics research in Igbo-ora and other developing countries.

Domains	Responses	
	Common responses	Less Common Responses
❖ Knowledge about current and past research in your community.	We participated in Malaria, Yellow fever, Guineaworm and Hypertension, and Onchocerciasis researches. We are not aware of any previous or ongoing genomics research. "I was part of the research team in Shekere, Geke and Shemi."	-No knowledge; "…one of it is Malaria research project which is even on-going"
❖ Any harm or injury due to community participation in research? Any "dishonour", "wrong" "exploitation" or "injury"?	Igbo-ora, as a community has no experience of harms due to genomics research. Some participants of Malaria Immunology researches were affected; "some farmers developed whitlow". Some died and our people thought it was due to the infection. In Guineaworm research: abate chemicals added into ponds polluted water bodies and killed many fishes; our people were offended. Some older villages felt dishonoured when "researchers" did not consult them and first dug boreholes for the newer villages in Igbo-ora. This could have been avoided with proper consultation.	In Igbo-ora researchers would not have problems about harms; research is seen as humanitarian.
❖ Do you think that genomics researches (about blood, lineage, human relatedness, tribe, race and ancestry, disease susceptibility, etc), are more sensitive than other researches? Explain more if you think this is the case.	Yes; this kind of research is more sensitive. Conflicts between ruling houses can occur because of such studies; People may be concerned about studies which may contradict beliefs about lineages. Such findings can affect ascension to kingship or other positions in the community; one ruling house may use such research finding against another. Yoruba communities believe they have a common ancestry and may not welcome any findings challenging this.	"Well, every research is sensitive; some are more sensitive than others"

Table 4.2 - contd.: Summary of the Key Informant Interview Participants' views about community harms in genomics research in Igbo-ora and other developing countries.

Domains	Responses	
	Common responses	Less Common Responses
❖ What concerns would you have if a genomics research is designed to be carried out in your community alone?	Yorubas will be interested on such studies. Igbo-ora people like research and will like to be the first. Stigmatization is of concern if the research could reveal a tendency to early death or health problem. We need somebody to guarantee that the research will not harm people especially if it is new. Will the researchers promise to tell us the results? Communication of the findings is a problem. This should follow community's values, like the reporting and interpretation of the results like the soothsaying of the "Babalawos".	People will receive genomics study because convulsion reduced in our place because of research. People extort money from us by coming to diagnose our diseases. Some dribbled us; collected blood from us and did not give us results.
❖ Are there concerns about the use of body fluids and body parts in research?	No concerns; people will even like to give their urine and saliva/sputum samples easily because of the benefits of treatment which Diabetes and TB patients have enjoyed in research.	
❖ If an ongoing research in your community has genomics components but you were not told about this before accepting to participate in it, how would you people react to this?	Nothing special; we may not abandon the research. Our people could write petitions against the study.	I believe researchers cannot harm or injure us, or the Igbo-ora people. They have our benefits in mind.
❖ If a research shows that your people could suffer a particular disease, or that some people have questionable ancestry. How would your community react especially if the study is published?		

Table 4.2 - contd.: Summary of the Key Informant Interview Participants' views about community harms in genomics research in Igbo-ora and other developing countries.

Domains	Responses	
	Common responses	**Less Common Responses**
❖ Have you ever felt that a research was debasing to you or your community? Or that the researchers were negligent? Has any research caused your community or individuals any harm?	No research was debasing to us. Our people were offended about the use of abate chemical in water. The decision to construct boreholes was also not discussed with the elders and some villages felt insulted.	People will receive genomics study because convulsion reduced in our place because of research.
❖ Do you have any knowledge about community harms that have occurred in other places due to research?	No we have not heard about problems with research in other communities. We have not heard of any community harmed by research elsewhere.	
❖ What does the governments at the 3 levels, hospitals and your community do to protect health research participants?	We are not aware of what the government or hospitals do to protect people. Our community addresses problems with research as they occur based on individual and family decision. When they see their people with unknown visitors or researchers, they caution them privately. They may take researchers and medical students to their Kabiyesi and Hospitals.	We know, just like you did for this study that researchers should get letter from Ministry of Health.

Table 4.2 - contd.: Summary of the Key Informant Interview Participants' views about community harms in genomics research in Igbo-ora and other developing countries.

Domains	Responses	
	Common responses	Less Common Responses
❖ How should injuries and harms to communities be addressed (prevented and resolved)? Are there any conditions you may give before participating in a genomics research in view of the concerns?	No research without the approval of Igbo-ora enlightened people. Obas, rulers and enlightened people should be consulted before sensitive research findings are published. Any ridiculous research or study that will make people unhappy should be avoided.	I am not enlightened. The enlightened people in the community should ask proper questions.
❖ Do you think your opinion on these can be recommended to other developing countries?	Yes; of-course.	
❖ Do you have any other concerns in your community about genomic research or health research generally?	No researcher except you has asked about injuries or harms due to research in Igbo-ora. This community is known for research in Nigeria and all-over the world. The Government should build a research centre/office for us in Igbo-ora so that records of research and discoveries like these will be kept in Igbo-ora.	

Table 4.3: Summary of the In-depth Interview Participants' views about community harms in genomics research in developing countries.

Domains	Responses	
	Common responses	**Less Common Responses**
❖ Have you participated in genomics research and ethical review of genomics research?	Yes- in terms of reviewing protocols; our centre has been involved in genomics studies; one study was done by Prof Clement Adebamowo and his team many years ago.	-
❖ Are genomics researches common in our environment?	Not very common, but "actually the experience is not low at all…. I would not say the experience is rare low or anything."	
❖ What are personal and Group harms from research generally;	Physical harms, like pain in the process of sample collection; Psychological and Social harms; Stigmatization is a psychological harm; not giving feedback to communities is also a type of harm. The issue of justice is important; why is the community selected for the research? If it is because of a wrong perceptions, that could be social harm. Not compensating the participants for their time and discomfort is psychological harm.	Feedback is demanded by communities but researchers fail to provide it.
❖ Do genomics researches have the same level of risks and harm as other researches?	There are greater risks of harms to the community because of some discoveries in individuals, for instance the predisposition to mental disease or cancer. "As for risks which implies potential danger or potential harms, genomics issues have more than an individual implication the risk especially when you have access to a pool from an identifiable group"	
❖ What are your concerns about engaging individuals and families/communities or tribes in genomics research?	If the findings are negative, they would cause stigmatization. The outcome is of concern and how the data is managed is critical, in terms of publication especially with respect to the confidentiality of the subjects.	
❖ Any concerns if a genomics research is to be done in your tribe alone?	How was my tribe chosen ,..what was the justification? How would the data be used?	

Table 4.3 – contd.: Summary of the In-depth Interview Participants' views about community harms in genomics research in developing countries.

Domains	Responses	
	Common responses	Less Common Responses
❖ Any concerns about genomics research in developing country compared to developed countries?	Taking full informed consent may not be easy in these studies in developing countries. How would results of genomics results be communicated to rural dwellers? Early premature commercialization of genomics findings and tests requires caution.	-
❖ Any experience with community harms in Nigeria or other developing countries? If yes, what factors could be responsible for such harms?	No; maybe because we do not have adequate information.	-
❖ Potential impact of harms; on individuals, groups, and society?	Because genes are involved; the findings of the study have implications not only for the individual but also for the relatives and family of the person.	
❖ Prevention and mitigation of community harms in community settings like Igbo-ora, and other parts of Oyo state?	Adequate ethical review and community engagement; the code developed by the national programme has sections expected to be fulfilled about genomics studies. Ethical committees should commence monitoring of research actively.	
❖ Do you think your opinion on this can be recommended to other developing countries?	An Oba or a Baale should be	

Section F: Appendices:

Appendix 1:

FOCUS GROUP DISCUSSION GUIDE.

Topic: Concepts of Community Harms In Genomics Research In Developing Countries; A Study In Oyo State, Nigeria.

Dear Participants,

The main focus of this exercise is to elicit your views as a group and as individual participants on the topic of discourse. Your acceptance to discuss these issues and your permission to have your voice recorded is a proof that you voluntarily consented to participate in this research. The discussion shall be guided using the outlines below, but you are all expected to re-confirm your perception of this research exercise:

* that your participation in this exercise is entirely voluntary?

* that you are not under any pressure to participate?

* that you understand that you could withdraw from this study at any point in time?

Please feel free to ask me your questions now or at any point during the discussion.

Thanks.

Discussion guidelines:

Introduction and recording of the consenting process; designation, background, expertise and experience, your age range, sex and profession and religion required. **No name, workplace or any other identifier needed.**

1. Have you participated in any research before? Or are you involved in an on-going research now? What is the research all about? Are you impressed or disappointed by the research process and/or outcome?
2. Have you ever felt “dishonoured”, “wronged” or “injured” in the process of participating in a research? Have you ever felt betrayed as an individual in the process of participating in any research? What happened?
3. Have you heard of any group of people or community wronged or injured in a research? Have you ever felt that your community has been wronged in the process of participating in any research?

4. Are there any members of your family or community, your people would not want to be involved in research because of your concerns about potential dishonor, wrong or injury? What about children, pregnant women, disabled patients etc? Do you have any concerns about their participating in research?

5. Are there ways in which your people, community, or family would not permit your body, or body fluids like blood, urine, saliva etc. to be used in research? What are your concerns about these?

6. If a research studies your blood, lineage, how you are related to your family members or kindred (tribe), and from where different people in your community originally came from (race), would you accept to be part of the research or not? What are your concerns about these?

7. If you did not know about these issues before participating in such a research, how would you feel and react if you discover them later? What would be the typical thing your community would do if such a thing happens here?

8. Assuming a research in your community, shows that your people suffer or could suffer a particular disease, or that your people are not from your traditionally known/accepted ancestry, what do you think about that? How would your community react? If such a study is published without the knowledge of your community, how would people respond to that?

9. If a study involves finding out your opinion about your tribe, race and community, are there any concerns you may have about participating in the study or allowing the study to be done in your community? Are there any conditions you may give before participating in such a research?

10. Have you ever felt that a particular research was debasing to you or your community? Or that the researchers were negligent of all or some things they should do? Can you give more details? Has the conclusion of any research caused your community or individuals any harm?

11. Have you ever heard of any group of people that were negatively affected by genomic research – blood research about origins of people, how diseases move from parents to offspring, etc.? Are there categories of people in the community you would not want to be part of such research? Why?

12. Do the people of your community have things they do to protect research subjects as a community? Are there things the health centres, hospitals and the government do to protect people involved in research against harms?

13. What are the things you think should be done to avoid problems when carrying out research about human origins and inheritance in your community.

14. Do you have any other concerns in your community about health research?

ITONI FUN IFOJUSUN APERO

Akori: Awon ewu towa ninu fifi eje se iwadi ni awon orile-ede ti oun dagba soke, eko lara ipinle oyo, ni Orile-ede Nijiria.

Mo ki eyin Olukopa,

Koko ifojusun ipade yii ni lati mo erongba yin gege bi egbe ati olukopa kookan lori akori ti an soro lee lori. Gbigba lati jiroro lori oro yii ati gbigba wa laaye lati gba oun yin sile fihan wipe efinnu findo lati kopa ninu iwadi yii. Ijiroro wa yio da lelori awon ifojusun ti alakale won yii, sugbon afe ki gbogbo yin so ero okan yin lori iwadi yii.

- Gbigba lati kopa je wipe efi tokan tokan yonda?
- Wipe kii se afipa se?
- Wipe oye re ye yin pe e le faa seyin ni kikopa ninu iwadi yii ni igbakugba tio ba wu yin?

Ejowo ele beere oun ti o ba ru yin loju nigba kugba ninu ijiroro yii.

E se pupo.

Awon Itoni fun Ijiroro wa:

Eto ifaara ati gbigba ohun sile ,ise yin, ibi ti etiwa, oun tie moose ati iriri yin pelu,ojo ori yin,okunrin tabi obinrin ati ise ti eyan laayo pelu esin yin. Ko si oruko ibi ise, tabi awon ti eba tun fe ka mo nipa yin.

1. Ikinni-----Nje eti kopa ninu iwadi kan ri? Tabi enkopa ninu iwadi kan ti oun lowo lowo bi? Kini iwadi naa da le lori? Se inu yin dun sii tabi eto ati abajade iwadi naa doju ti yii bi?

2. Ekeji----- Nje ati seyin ni ijamba ri nipa se kipopa ninu iwadi bi? Nje o ti ba ijakule pade gege bi enikan nipase kikopa ninu iwadi bi? Ki lo se le gan an?

3. Eketa---- Nje o ti gbo nipa awon eniyan kan tabi agbegbe kan ti o nu iwa buburu ni gba ti won se iwadi bi? Nje o han si e wipe won ti se agbegbe yin ni ijamba nipase kikopa ninu iwadi kan ri?

4. Ekerin---- se o ni enikan ninu ebi re ,tabi agbegbe ti owa lara awon eniyan re ti o kofe kio kopa, ninu iwadi yii nitori irunu re lori awon ewu ti o le wa? A won omode nko, aboyun, awon aro ati beebeelo? Se o ni ijaya Kankan lori ikopa won ninu iwadi yii?

5. Ekarun---- se awon ona wa ti awon ara ile re, tabi ebi re, koni je ki ara ,tabi omi ara re bii eje, ito, ito ati beebeelo kopa ninu iwadi ? Kini erongba re lori awon nkan won yii

6. Ekefa---- se o le gba tabi ko lati kopa ninu iwadi ti eko ijile ba wa lori eje, ibatan, bi o se tan mo ebi tabi eya, ati ibiti awon oni runrun eniyan ninu agbegbe re se sewa.

7. Ekeje---Bawo ni ose ma wuwa ti o ko ba mo awon ewu won yii ki o to kopa ninu iwadi iru eyii sugbon ti o wa mo leyin ore yin? Kini pato awon ara agbegbe yio se ti iru nka bayi ba sele ni bi yii.
8. Ekejo—Kini ero ti iwadi ba fihan ninu agbegbe re ,awon eniyan re se aisan, tabi won le ni arun kan pato, tabi pea won eniyan re ko tan mo iran re ? Bawo ni ilu re se maa gbaa? Ti a ba tan iroyin naa ka ki won to mo, kini iha ti awon eniyan re, se maa ka si?

9. Ekesan---- Nje o ni ijaya Kankan lori ki kopa ninu iwadi tabi fifi aye gba iwadi ninu agbegbe re bi ?ti e ko ba je mo iwadi lori erongba okan re lori eya, iran ati ilu re ? se ilakale wa ki o to kopa ninu iwadi iru eyii?

10. Ekewa--- Nje o han si o tabi agbegbe re pe iwadi kan renisile ri bi? Tabi awon oluwadi ko ko bi ara to dara si gbogbo tabi awon nkan ti o ye ki won se? se o le fun wa ni awon alaye kikun? Nje asekagba iwadi kan ti inu ijamba ba agbegbe re tabi enikeni bi ?

11. Ikokonla----Nje oti gbo nipa awon eniyan kan ti won ti ni iriri isele aburu nipa iru iwadi bayi.

    Nje iwadi eje je nipa isedale eniyan bi?

    Se o je bi arun se oun tari lara obi sii omo bi? Ati beebeelo,

    Nje awon kan wa ninu agbegbe re ti oko fe ki o kopa ninu iwadi iru eyii bi? Kini idi re?

12. Ikejila –nje agbegbe re ni ikan asiri ti won kofe ki o je ara iwadi bi? Nje oun koun wa ti ijoba , ati awon iloe iwosan abele , ati ti ijoba nse lati daabobo awon oluwadi bi?

13. Iketala----- kini awon oun ti o ro wipe o ye ni sise lati dena ewu ti a ba n se iwadi nipa isedale eniyan ati ajogunba ni a gbegbe re?

14. Ikerinla—Nje oni afisokan miran nipa oro ilera ni agbegbe re bi?

Appendix 2:

KEY INFROMANT INTERVIEW GUIDE: for Community Leaders.

Topic: Concepts of Community Harms In Genomics Research In Developing Countries; A Study In Oyo State, Nigeria.

Dear Respondent,

Kindly peruse these itemized points about the "***Concepts of Community Harms in Genomics Research in Developing Countries***." This guide will form the basis of the discussion we will have on the topic. You are free to comment on the issues and other related ones you may know. The order need not necessarily be followed. Your acceptance to discuss these issues and your permission to have your voice recorded is a proof that you voluntarily consented to participate in this research. It is also well-accepted that:

* your participation in this exercise is entirely voluntary.

* you are not under any pressure to participate.

* you understand that you could withdraw from this study at any point in time.

Please feel free to ask me your questions now or at any point during the interview.

Thanks.

Introduction and recording of the consenting process; designation, background, expertise and experience, your age range, sex and profession and religion required. **No name, workplace or any other identifier needed.**

1. Do you know of any on-going research in your community? If yes, what is it all about? Are you impressed or disappointed by the research process and/or outcome? Do you know about members of your community who are engaged in any research?
2. Has there been any harm or injury suffered by a member of your community for participating in any research? Has anybody or community you know ever felt "dishonoured", "wronged" "exploited" or "injured" in the process of participating in a research? If yes, what happened?
3. Do you think that an individual or community could be "dishonoured", "wronged" "exploited" or "injured" in the process of participating in a research? How could this happen and how would your community respond to that? Has any such instance happened before?
4. With respect to your community's values and belief, do you think that participating in researches about blood, lineage, how one is related to his/her family members or kindred (tribe), and from where different people in your community originally came from (race), are more sensitive than other researches? Explain more if you think this is the case.
5. If a researcher wants to carry out a study in your tribe alone (out of many others), would you be concerned about any issue? What information would you need to be given before you could decide to support or reject a research that involves your tribe or other tribes of Nigeria?

6. Are there ways in which your people, community, or family would not permit your body, or body fluids like blood, urine, saliva etc. to be used in research? What are your concerns about the use of body fluids and body parts in research?

7. If a research studies your blood, lineage, how you are related to your family members or kindred (tribe), and from where different people in your community originally came from (race), would you accept to be part of the research or permit your people to be part of the study?

8. If you did not know about these issues before participating in such a research, how would you feel and react if you discover them later? What would be the typical thing your community would do if such a thing happens here?

9. Assuming a research in your community, shows that your people suffer or could suffer a particular disease, or that your people are not from your traditionally known/accepted ancestry, what do you think about that? How would your community react? If such a study is published with or without the knowledge of your community, how would people respond to that?

10. If a study involves finding out your opinion about your tribe, race and community, are there any concerns you may have about participating in the study or allowing the study to be done in your community? Are there any conditions you may give before participating in such a research?

11. Have you ever felt that a particular research was debasing to you or your community? Or that the researchers were negligent of all or some things they should do? Can you give more details? Has the conclusion of any research caused your community or individuals any harm?

12. Have you had any experience with problems that cropped up in any other community because of a research conducted with members of the community? If yes, what factors could be responsible for such harms?

13. Do the people of your community have things they do to protect research subjects as a community? Are there things the health centers, hospitals and the government do to protect people involved in research against harms?

14. In your opinion, (in consideration of the values of your people) how should injuries and harms to communities be addressed (prevented, resolved) in places like your community, and other parts of Oyo state? Do you think your opinion on these can be recommended to other developing countries?

15. Do you have any other concerns in your community about genomic research or health research generally?

Appendix 3:

IN-DEPTH INTERVIEW GUIDE: for REC members and Researchers.

Topic: Concepts of Community Harms In Genomics Research In Developing Countries; A Study In Oyo State, Nigeria.

Dear Respondent,

Kindly peruse these itemized points about the "***Concepts of Community Harms in Genomics Research in Developing Countries***." This guide will form the basis of the discussion we will have on the topic. You are free to comment on the issues and other related ones you may know. The order need not necessarily be followed. Your acceptance to discuss these issues and your permission to have your voice recorded is a proof that you voluntarily consented to participate in this research. It is also well-accepted that:

* your participation in this exercise is entirely voluntary.

* you are not under any pressure to participate.

* you understand that you could withdraw from this study at any point in time.

Please feel free to ask me your questions now or at any point during the interview.

Thanks.

1. Introduction and recording of the consenting process; designation, background, expertise and experience, your age range, sex and profession and religion required. **No name, workplace or any other identifier needed.**

2. Specific research activities:

   Have you participated in genomics research? Do you have any interest in genomics research? Any experience in bioethics or ethical review of research?

3. Perception of risks and harms to communities in research generally compared to genomics research.

   - What harms can occur to a person and/or groups by virtue of their involvement in research generally?
   - If the research is on genomics, do you think the same harms apply? Are there other harms peculiar to genomics research and genetic testing in your opinion?
   - If you were to participate in a genomics research as an individual research subject, what would your concerns be with respect to risks/harms to you as an individual and to your family or tribe or community?
   - If a researcher wants to carry out a study in your tribe alone, would you be concerned about any issue?
   - What information would you want to have to support a genomics research in your tribe alone or in all the tribes of Nigeria?
   - If a particular genomic research is to be carried out in a developing country and a well-developed country, do you think, the concerns of people in a developing country would/should differ from those of the people in a developed or western society?

4. Have you had any experience with community harms or heard about any instance of these in Nigeria or other developing countries?

   - If yes, what factors could be responsible for such harms?
   - What is the extent of the potential impact of such harms; on individuals, groups, and society?
   - In your opinion, how should community harms be addressed (prevented, resolved) in community settings like Igbo-ora, and other parts of the state?
   - Do you think your opinion on this can be recommended to other developing countries?