ETHICAL IMPLICATIONS OF GENOMICS TESTS: A DEONTOLOGICAL-UTILITARIAN EXAMINATION

BY

ORJI, CLETUS OKWUCHUKWU

MATRIC NO: 173052

BEING A DISSERTATION SUBMITTED TO THE FACULTY OF CLINICAL SCIENCES, DEPARTMENT OF SURGERY, UNIVERSITY OF IBADAN, IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF THE DEGREE OF MASTER OF SCIENCE IN BIOETHICS

JULY, 2014

CERTIFICATION

This is to certify that this dissertation entitled: **ETHICAL IMPLICATIONS OF GENOMICS TESTS: A DEONTOLOGICAL-UTILITARIAN EXAMINATION**, Submitted to the Faculty of Clinical Sciences, Department of Surgery, University of Ibadan, Ibadan, for the Award of the Degree of Master of Science in Bioethics, is an original research carried out by **ORJI, CLETUS OKWUCHUKWU**

SUPERVISORS:

DR. (MRS.) BOLATITO LANRE-ABASS
Senior Lecturer, Department of Philosophy
University of Ibadan
Ibadan

DR. PAUL AKIN-OTIKO, OP
Senior Lecturer, Dominican
Institute of Philosophy and
Theology, Samonda, Ibadan

DEDICATION

This work is dedicated to the Triune God — Father, Son and Holy Spirit; and to the Blessed Virgin Mary, Our Mother of Perpetual Help.

ACKNOWLEDGEMENT

My sincere gratitude goes to the Almighty God for His immeasurable assistance towards the completion of this research project. I express my deep and honest appreciation to my supervisors, Dr. (Mrs.) Bolatitito Lanre-Abass and Dr. Paul Akin-Otiko, OP, for their guidance and great contributions towards the successful completion of this project.

My special thanks go to Prof. Clement Adebamowo who made this study possible through a grant (D43TW007091) from the United States National Institutes of Health, Forgarty International Centre and National Human Genome Research Institute. My profound gratitude goes to Dr. Temidayo Ogundiran whose help and advice made this project a reality. Sir, I thank you.

My appreciation also goes to the Administrator of this program, Dr. Stella Ogundipe, for the good works she is doing in West African Bioethics Training Program (WAB) and for her help towards the completion of this project. I am also grateful to all the lecturers that taught me in this program, for their time and energy towards making the program a success.

Finally, I thank all scholars whose ideas helped me in producing this work. I pray that the Almighty God, in His infinite love and mercy, will abundantly bless, reward and grant your fondest hearts' desires. Thanks to you all!

TABLE OF CONTENT

CHAPTER ONE: GENERAL INTRODUCTION

1.1 BACKGROUND OF THE STUDY

The term “genomics” can be defined as “the study of genes and their functions”(World Health Organization, 2002). It is “the study not just of single genes, but of the functions and interactions of all the genes in the genome”(Guttmacher & Collins, 2002). Hence, genomics, unlike genetics, is used for the analysis of multiple genes or proteins. The field of genomics evolved over the last few decades in large part due to advances in sequencing technology, as well as information and communication technology. The evolvement of this field holds tremendous promise for the prevention, diagnosis and treatment of some of the major diseases affecting humankind. This includes malaria and tuberculosis, as well as non-communicable diseases such as diabetics, cancer and cardiovascular disease. Genomics helps to understand the genetics of bacteria, plants, and animals(Genomics and Global Health: A Report of the Genomics Working Group of the Science and Technology Task Force of the United Nations Millennium Project, 2004).

Genomics is very important in the areas of developing drugs, designing of new drugs, vaccines and DNA diagnostics. As a result of its importance, it has created new opportunities for drug discovery. This is because the knowledge of human genes and their functions may not only allow effective preventive measures, but also may change drug research strategy and drug discovery development processes.

Genomics test is that test that analyses human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes(Hoff et al., 2000). The test is carried out for different reasons which include but are not limited to the diagnosis of disease in newborn babies, children and adult;

the identification of future health risks; the prediction of drug responses; and the assessment of risks to future children(Hoff et al., 2000). Genomics test has contributed immensely to the knowledge of human health and diseases. Not only in ensuring that the present health status of a person who undergoes the test is known, but it also aids in knowing whether or not the person is at risk of a particular disease.

Genomics test is capable of revealing a lot of information such as the presence of heritable disease (of varying severity – treatable, untreatable, stigmatizing and non-stigmatizing). The implication of this is that when genomics test result of someone shows that he/she is at risk of a particular disease, it immediately suggests the possibility that the family members or blood relatives of the person are also at risk(Juengst, 2004).

1.2 STATEMENT OF THE PROBLEM

Genomics test can reveal sensitive and enormous information about an individual who undergoes the test as well as his/her family members or blood relatives. Hence, genomic information of a person could expose not only the person but also his/her family members or blood relatives to harm if the information gets to a wrong hand.

Genomics test is a recent phenomenon in Africa. Consequently, Africans may not have ready access to interventions that would change the results of their genomics test if the results show that they are at risk of certain diseases. This raises some fundamental questions concerning the ethical implications of conducting the test in Africa and whether or not health care professionals who carry out the test have obligation to provide the required interventions.

The goal of research is to generate a generalizable knowledge, which genomics research/test is not an exception. But the fundamental question in the process of conducting research (for example, genomics research/test) is: how does one ensure that individuals who take part in it are not used as a mere means to an end? This study would examine the ethical implications of genomics test from the perspectives of deontology and utilitarianism.

1.3 RESEARCH AIM AND OBJECTIVES

The primary aim of this study is to examine the ethical implications of genomics tests from the viewpoints of deontology and utilitarianism. The study would specifically:

1. Examine genomics and the kind of information it reveals;
2. Identify and examine the ethical issues that are likely to arise in carrying out genomics tests;
3. Discuss the ethical implications of genomics tests using Immanuel Kant's deontology and Jeremy Bentham's utilitarianism as a tool; and
4. Attempt to resolve the problems raised in this study by recommending ways to overcome them.

1.4 RELEVANCE AND JUSTIFICATION OF THE STUDY

This research work helps to bring to the fore the ethical implications of genomics tests in Africa. The study also looks at the ethical implications of genomics tests from the points of view of deontology and utilitarianism as emphasis has not been placed on the ethical implications of genomics tests from the perspectives of these ethical theories. It is therefore hoped that the study

would provide ethical guide for researchers in designing and conducting genomics research/test in Africa.

1.5 METHOD OF THE STUDY

This study is an analysis of the ethical implications of genomics tests from the viewpoints of deontology and utilitarianism. These two ethical theories have been chosen to enable a comprehensive analysis of the ethical implications of genomics tests. The theories would complement each other, the arguments lacking in one theory would be provided by the other. Immanuel Kant's deontological approach would be adopted while Jeremy Bentham's utilitarian approach would be relevant for the purpose of this study. But before delving into the views of the aforementioned philosophers in their respective schools of thought, let us briefly look at the two ethical theories – deontology and utilitarianism.

1.5.1 DEONTOLOGY

Etymologically, the term "deontology" is derived from two Greek words - *deon* which means "duty" and *logos* meaning "science". Deontology, therefore, literally means the science of duty(Olson, 1967). In the current usage, the meaning of deontology is more specific: it is an ethical theory which holds that at least some acts are morally obligatory irrespective of their consequences for human weal or woe(Olson, 1967). In other words, deontology is an ethical theory that teaches that the morality of an action should be based on whether the action itself is right or wrong under a series of rules, rather than based on the consequences of the action.

The theory has it that some acts are intrinsically right (right in themselves) and thus ought to be done, while others are intrinsically wrong (wrong in themselves) and as a result ought to be

avoided. Deontologists neither believe that good and right could be used interchangeably nor believe that good is prior to right. In their belief, the right is not to be defined in terms of the good, and they vehemently reject the view that the good is prior to the right. The goodness of the ultimate consequences, for the deontologists, does not guarantee the rightness of the actions which produced them. In accordance with the deontologists, the two realms are not only distinct, but the right is prior to the good(Fried C., 1978).

Deontological idea is one that requires agents to avoid doing things that are wrong even when they foresee that their refusal to do such things will clearly result in greater harm (or less harm). For instance, from a deontological perspective, it is not the bad consequences of a particular lie that makes it wrong, lies are wrong because of the sorts of things they are, and are thus wrong even when they foreseeably produce good consequences(Davis, 1991).

Deontological theories, therefore, "are based on the view that there are certain sorts of acts that are wrong in themselves, and thus they are morally unacceptable, even if the ends which are being pursued are morally admirable"(Walsham, 1996). Deontology is a normative ethical theory that judges the morality of an action based on the action's adherence to a rule or rules. The theory is sometimes described as "duty" or "obligation" or "rule" – based ethics. This is as a result of the fact that rules "bind you to your duty"(Bruce, 2005).

1.5.2 UTILITARIANISM

Generally, the term "utilitarianism" refers to the ethical theory which holds that the rightness or wrongness of actions is determined by the goodness or badness of their consequences(The Encyclopedia of Philosophy, Vol. 7, 1967). It is an ethical theory that teaches

that an action is morally right if the consequences of the action are more favorable than unfavourable to the greatest number of people (Brandt, 1992). This ethical principle sees that which brings happiness as good, and that which causes pain as bad. An action, therefore, is judged to be right or ethical if it produces pleasure or happiness to the greatest number of people; it is seen as wrong or unethical if it produces pain to the greatest number of people.

1.5.2.1 Act Utilitarianism

Act utilitarianism claims that an action is right if it maximizes happiness; otherwise, it is wrong. It has it that the goal of our actions should be the greatest happiness, what we hope to bring about. Here, actions are judged not in themselves, that is, what sort of actions they are, but in terms of what consequences they have(Lacewing, 2014).

Greatest happiness is comparative (great, greater and greatest). If an action leads to the greatest happiness for the greatest number of people it affects, no other action taken at that time could have led to greater happiness. For this reason, an action is right on the condition that, out of all the actions one could have done, this action leads to greatest happiness for the greatest number of individuals involved in it. In judging whether or not an act is morally right, an act utilitarian considers the consequences of different actions one could perform and choose the one that brings about the greatest happiness(Lacewing, 2014). Act utilitarianism applies the principle of utility (the principle of greatest good, happiness and pleasure) to individual actions. It looks at the consequences

of each individual action and calculates utility each time the action is performed(Hinman, 2014).

1.5.2.2 Rule Utilitarianism

The claim of rule utilitarianism is that an action is right if and only if it complies with those rules which, if everybody follows them, would lead to the greatest happiness(Lacewing, 2014). Rule utilitarianism, unlike act utilitarianism that applies the principle of utility to individual actions, applies the principle of utility to moral rules. It looks at the outcomes of having everyone follow a particular rule and calculates the overall utility of accepting or rejecting the rule(Hinman, 2014).

1.5.3 IMMANUEL KANT ON DEONTOLOGY

Immanuel Kant (1724-1804) is a deontologist who strongly believes that to act in the morally right way, people must act from duty. Duty, according to him, is the necessity of an action from respect for the law(Kant, 1785). Kant also holds that the rightness or wrongness of actions does not depend on the consequences of the actions. This view, no doubt, is apparently in opposition to the utilitarian theory that teaches that an action is right if it produces greatest happiness to the greatest number of people. Kant's argument that to act in the morally right way one must act purely from duty begins with an argument that the highest good must be both good in itself and good without qualification(Kant, 1797). A thing is said to be good in itself when it is intrinsically good, and good without qualification, when the addition of that thing never makes a situation ethically worse.

Hence, for Kant, those things that are usually thought to be good, such as intelligence, perseverance and pleasure, fail to be either intrinsically good or good without qualification. Pleasure, for instance, seems to not be good without qualification. This is because when people take pleasure in watching someone suffering, this appears to make the situation ethically worse.

Kant therefore draws a conclusion that there is only one thing that is truly good: “Nothing in the world – indeed nothing even beyond the world – can possibly be conceived which could be called good without qualification except a good will”(Kant, 1785).

According to Kant, the consequences of an act of willing cannot be used to determine that a person truly has a good will. He asserts that good consequences could arise by accident from an action that was motivated by a desire to cause harm to an innocent person, and bad consequences could arise from an action that was well-motivated. For this reason, Kant maintains that the only thing that is truly good in itself is a good will, and a good will is only good when the person who wills, chooses to do something because it is his duty. Kant conceives the concept of respect as “the concept of a worth which thwarts my self-love”(Kant, 1785).

1.5.3.1 The Categorical Imperative

Kant argues that moral requirements are based on a standard of rationality which he termed the “Categorical Imperative”. The Categorical Imperative, according to him, is the supreme principle of morality. It tells one what he/she should always do in any situations the person finds himself/herself. The Categorical Imperative is of two forms: the Universal Law Formulation and the Respect for Persons’ Formulation.

The first form, the Universal Law Formulation, says: “Act only in accordance with that maxim through which you can at the same time will that it become a universal law’’(Kant, 1785). The implication of this is that one is not allowed to do something that he/she would not be willing to allow any other person to do as well. One is forbidden to make exceptions for himself/herself. For example, if one expects other people not to go contrary to the promises they

make, the person should as well keep his/her own promises. The idea here is that one should only act on the maxims that are universalizable. A thing is said to be a maxim if and only if it tells one what to do and reason why the person should do it. Something is universalizable on the condition that everyone could follow it and succeed in what he/she does.

The second form, the Respect for Persons' Formulation, articulates: ''Act so that you use humanity, as much in your own person as in the person of every other, always at the same time as end and never merely as means''(Kant, 1785). The Categorical Imperative, therefore, is "a form of ultimate test as to whether an action is right or wrong"(Davison, 2002). According to Spinello, the Respect for Persons' Formulation of the Categorical Imperative "can be reduced to the absolute principle of respect for other human beings, who deserve respect because of their rationality and freedom, the hallmark of personhood for Kant"(Spinello, 1995).

"Persons", in Kantian ethics, refers to any being with the capacity to make moral judgments and conform to them (where that often requires that one resists various urges, inclinations, and temptations to act against them). Persons have free will and reason. It is only persons that possess "dignity" and must be treated as "ends". Animals, according to Kant, only have a "use value" and may be treated as mere means or resources(Driver, 2007). Animals may be used in experiments to test new drugs. "Persons" may as well be used in such experiments but only with their "informed consent".

Kant rejects the doctrine of utilitarianism which postulates that an action is right if it maximizes happiness to the greatest number of people. He maintains that there are many circumstances when maximizing utility would be wrong. For instance, a surgeon has one healthy

and five sick and dying patients. Each of the sick and dying patients needs a new organ – one a new kidney, another, a new liver, the third a new heart, and so forth – and would fully recover if he/she received it. It happens that the healthy patient would be a suitable organ donor for all the sick and dying patients. If the surgeon kills the healthy patient and redistributes his/her organs, he/she saves five persons. If he/she does not do anything, then the healthy patient lives while the five sick patients die. In this situation, if the surgeon kills the healthy patient to save the lives of the five sick patients, Kant would judge the act to be wrong, irrespective of the fact that it maximizes utility for the greatest number of people. Kant would see this as wrong due to the fact that it treats the person in question as a mere means to the ends of others.

Kant's point on the Principle of Respect for Persons is that one should always treat others in the ways that they would not object to if they are morally reasonable and well-informed about relevant factual matters.

1.5.3.2 Kant on Lying

Lying, according to Kant, is typically wrong. He insists that one should always act only according to that maxim by which one can at the same time will that it should become a universal law. By "maxim", Kant means a general rule that governs an act.(Pence, 2007) Kant believes that human culture can neither exist nor thrive when lie becomes a routine thing by most people. For him, if everyone routinely lies, communication and shared endeavours would be impossible. He argues that it is irrational to think that practices such as promising and talking can continue when most people lie most of the time; for it is contradictory to think that these practices are compatible with routine lying. Thus, Kant maintains that rationality and morality go hand in hand.(Pence, 2007)

In the context of this research, to allow physicians to lie to patients about a diagnosis of cancer or any serious disease would be unethical. If the maxim says, lie to patients when the truth is unlikely to do them any good or lie to patients when one may get sued for making a mistake, then such lie weakens all communication in medicine between doctor and patient.

Lie undermines all trust between physicians and patients. As a result, Kant would argue that such practice damages the margins of the physician-patient communication. As harm, one lie to a patient probably does not do much damage. But according to Kant, the deception goes much deeper because it strikes at the very heart of all communication(Pence, 2007).

In a situation where lying to evil people would help to thwart their evil aims (for instance, when an assassin asks for the whereabouts of the person he/she wants to kill), Kant still stands his ground that lying remains wrong. To be truthful, Kant claims, is "a sacred and absolutely commanding decree of reason, limited by no expediency"(Kant, 1797). Commenting on this, Sissela Bok submits, "to breach that decree is to injure the system of communication among human beings and thus to endanger the very foundations of duty"(Bok, 1988).

1.5.4.1 JEREMY BENTHAM ON UTILITARIANISM

1.5.4.2 The Principle of Utility

Utilitarianism is said to have originated from Jeremy Bentham (1748-1832). In one of his famous books entitled *Magnum Opus*: *An Introduction to the Principles of Morals and Legislation*,(Bentham, 1789) he holds that utilitarianism is an ethical theory which influences one to act in a way that will produce the greatest happiness for the greatest number of people. For Bentham, therefore, an action is right based on the condition that it promotes the greatest amount of happiness. But, it is wrong if it produces bad consequences which are intrinsically the reverse

of happiness. As a matter of fact, the rightness of such an act depends not only on the effects it has on the performer of the action, but also on everyone directly or indirectly affected by it.

The ethical theory of utilitarianism cannot be separated from the principle of utility, the principle of greatest good, happiness and pleasure. Emphatically, it is the bedrock of Bentham's concept of utilitarianism. In articulating this principle as that which guarantees the pleasure and happiness of the greatest number of people, Bentham defines it as: "That principle which approves of every action, whatsoever, according to the tendency which it appears to have to augment or diminish the happiness of the party whose interest is in question; or what is the same thing in other words to promote or to oppose happiness"(Bentham, 1789).

Bentham sees this principle as that which is of greater relevance in guaranteeing the greatest amount of greatest happiness based on the fact that "nature has placed mankind under the governance of two sovereign masters: pain and pleasure"(Bentham, 1789). Since utility implies happiness or pleasure for Bentham, the constant search for happiness and pleasure becomes the driving force for all his action. Consequently, utility becomes the moral standard, the criterion and the yardstick for differentiating between good and bad actions. Bentham held that while pleasure and happiness are the only good that can be desired and longed for by human beings, pain, is the only evil human beings seek to avoid.

1.5.4.2 Bentham on Pain and Pleasure

Bentham made a distinction between pain and pleasure. According to him, the major distinction between pain and pleasure is based on the simple-complex criterion. He holds that there are some aspects of pain and pleasure that are simple, while there are some that are complex. Pain

and pleasure are simple when they cannot be multiplied into more aspects, while the complex ones are considered to be those that can be resolved into diverse simple ones(Bentham, 1789). Nevertheless, a more concrete distinction between the simple and complex aspects of pain and pleasure is based on the fact that: "What determines a lot of pleasure, for example, to be regarded as one complex pleasure rather than as diverse simple ones is the nature of the exciting cause, whatever pleasures are excited all at once by the action of the same cause are apt to be looked upon as constituting all together but one pleasure"(Bentham, 1789).

In his hedonistic calculus, inter alia, Bentham includes intensity, duration, certainty, propinquity, fecundity, purity and extent (that is the number of people it extended to or who are affected by it) as criteria for what choice of pleasure to be made.

Intensity: This requires an individual to choose that which would give a more intense and lasting pleasure as against an option that results in a less amount of pleasure and also yearns for that which would amount to a less intense pain as against the more intense one.

Duration: The duration of the pleasure should be considered such that an individual prefers a pleasure that lasts longer to the one that has short life-span.

Certainty: This criterion says that one must prefer the pleasure that is more certain to the one that is less probable.

Propinquity: The nearness of pleasure with regard to space and time should be considered. Hence, the pleasure that is nearer should be preferred to the one that is far away in distant future.

Fecundity: The pleasure that is capable of producing or leading to further pleasure should be preferred to that which is non-productive. Thus, pleasure becomes less important if it cannot lead to further pleasures.

Purity: This criterion says that the pleasure that is not mixed with pain should be preferred to the one that is garnished with pain. This shows that pain and pleasure are in opposition to each other and therefore cannot work hand in hand.

Extent: This criterion is considered to be the hallmark of the ethical theory of utilitarianism. It stresses that the pleasure that can be enjoyed by the greatest number of people should be preferred to that which is enjoyed by a smaller number of people.

CHAPTER TWO: LITERATURE REVIEW

2.1 What is Genomics?

Genomics can be defined as the study of the genomes of organisms. The primary aim of genomics is to find out the whole sequence of DNA or the composition of the atoms that constitute the DNA and the chemical bonds between the DNA atoms(Genomics in Theory and Practice, 2012). The study of genomics includes understanding how the genome interacts with environmental or non-genetic factors, such as a person's lifestyle. It has the potential to improve our understanding of complex diseases such as diabetes, heart disease, and asthma, as well as improve medical treatment. Unlike monogenic diseases, most of the conditions that affect large groups of people, such as cancer, diabetes, and cardiovascular disease, are more complicated. These diseases are caused by variations in more than one gene or by multiple genes interacting with each other and the environment. Testing for and treating complex diseases presents challenges, but genomics can help. Genomics focuses on all of the genes and genetic material as a dynamic system. By understanding how genes interact with non-genetic factors over which people have control, such as diet, exercise, and smoking, we may one day be able to prevent some complex diseases(Center for Genomics and Public Health, 2011).

Genomics, in reality, is different from genetics and should not be confused with it. The main difference between genomics and genetics lies on the fact that while genomics, on the one hand, addresses all genes and their inter-relationships in order to identify their combined influence

on the growth and development of the organism, genetics, on the other hand, scrutinizes the functioning and composition of single gene(World Health Organization, 2014).

2.2 History of Genomics

Genomics is a new field of enquiry. The concept of genomics was coined in 1986 by Dr. Tom Roderick, a geneticist at the Jackson Laboratory, at a meeting held in Maryland on the mapping of the human genome(Yadav, 2007). Although the DNA was first isolated as early as 1869, it took more than one century for the first genomes to be sequenced. History of modern genomics started in the 1970s, though with the help of important discoveries in the field by a small group of scientists shortly after the Second World War(Genomics in Theory and Practice, 2012).

Technological advances in the 1950s such as the creation of isotopes and radiolabel biological molecules helped modern genomics. The description of the structure of the DNA helix by James D. Watson and Francis H. C. Crick in 1953 also contributed immensely to modern genomics. This allowed determination of the DNA replication, gene expression, protein synthesis, and so on. Later, technological advances and advances in methodology such as the automated DNA sequencing and polymerase chain reaction (PCR) developed in the early 1980s made a useful contribution in the field of genomics. Both automated DNA sequencing and PCR played the key role in the Human Genome Project which, however, was completed only in 2007(Genomics in Theory and Practice, 2012).

In the early 1970s, Frederick Sanger sequenced the first genome. He sequenced the genomes of a virus and mitochondrion. Sanger and his colleagues also created techniques for

sequencing, data storage, genome mapping and other techniques and methodologies which still play an important role in genomics(Pevsner, 2009).

Another scientist who played a vital role in modern genomics was Walter Fiers. In 1972, Fiers and his research group, from the Laboratory of Molecular Biology of the University of Ghent in Belgium, became the first to sequence a gene. They sequenced the gene of Bacteriophage MS2. For this reason, Bacteriophage MS2 became the first organism to be completely sequenced(Fiers, et al, 1972).

Hamilton O. Smith and his research team from The Institute for Genomic Research, in 1995, became the first to sequence a genome of a free living organism – that of Haemophilus influenzae. Since then, genomes of various organisms including that of human beings (mostly sequenced in 2001, completed in 2007) have been sequenced at a great pace. Presently, we have complete sequences for more than 2,700 viruses, over 1,000 bacteria and archaea and 36 eukaryotes, with the new ones being sequenced virtually on a daily basis(Genomics in Theory and Practice, 2012).

2.3 The Main Genomics Research Areas

Over the last few decades, genomics research projects gave rise to several research areas in the study of genomes. They include:

2.3.1 Human Genomics

Human Genomics is concentrated on the application of genomic analysis in all aspects of human diseases, as well as the genomic analysis of adverse drug reactions, drug efficacy and safety(Springer, 2014).

2.3.2 Bacteriophage Genomics

Bacteriophage genomics is the study of bacteriophage genomes or genomics of viruses which infect bacteria and are considered as a possible alternative for treatment of ailments that are caused by antibiotic-resistant bacteria(Genomics in Theory and Practice, 2012).

2.3.3 Metagenomics

Metagenomics is the study of metagenomes or genetic material that is obtained from environmental samples rather than from cultivated cultures(Genomics in Theory and Practice, 2012). It is a genomic analysis of microbial communities. Metagenomics provides access to organisms that are recalcitrant to culturing, as are the vast majority of Microorganisms on Earth(Handelsman, 2007). It has revolutionized the understanding of microbial world and has shown that the traditional cultivation techniques have missed the majority of microbial diversity(Genomics in Theory and Practice, 2012).

2.3.4 Cyanobacteria genomics

Cyanobacteria genomics is an area in genomic research that focuses on the study of cyanobacteria, a phylum of bacteria that gets energy via photosynthesis(Genomics in Theory and Practice, 2012).

2.3.5 Pharmacogenomics

Pharmacogenomics is the study of how genes affect an individual's response to drugs. It combines pharmacology (the science of drugs) and genomics (the study of genes and their functions) to develop effective, safe medications and doses that will be tailored to a person's genetic makeup(Genetics Home Reference, 2014). Pharmacogenomics ascertains the influence of genomic variation on drug response(Hunter, et al., 2008). It examines a person's genes to understand how drugs may move through the body and be broken down. Many drugs that are currently available are produced for everyone but they do not work the same way for all human beings. It is difficult to predict who will benefit from a medication, who will not respond at all, and who will experience negative side-effects called adverse drug reactions(Genetics Home Reference, 2014). The goal of pharmacogenomics, therefore, is to select drug treatments that are best for each person. It enables people to get the right dosage of medication based on their particular genetic makeup(Kailos Genetics, 2013).

2.4 What is Genomics Test?

Genomics test can be defined as the test that analyses human DNA, RNA, chromosomes, proteins, and certain metabolites so as to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes(Hoff, et al., 2000). The test is capable of revealing a lot of information about a person's genes and chromosome and their association with risk of health and disease throughout life. Genomics test is done for many reasons which include(Hoff, et al., 2000) the diagnosis of disease in newborn babies, children and adult; the identification of future health risks; the prediction of drug responses; and the assessment of risks to future children.

Genomics testing has made enormous contribution to the knowledge of human health and diseases. With the successes recorded from genomics testing, scientists now know that genome and particular genomes play an important role in an individual's susceptibility to particular diseases. By determining the risk of a person's vulnerability to a particular condition, measures can be taken to prevent the disease from occurring or help the person to reduce the risk of developing that particular illness.

2.5 Ethical Principles Governing Genomics Tests

Genomics test, as noted above, is capable of revealing enormous information (both discriminating and non-discriminating, stigmatizing and non-stigmatizing, and so on) about the individual that undergoes the test as well as his/her blood relatives. As a result of this, it is imperative that such test be conducted in a manner that follows certain ethical principles and procedures in order to minimize harm and maximize benefits to individuals directly or indirectly involved in the test. In conformity with the Declaration of Helsinki (adopted by the World Medical Assembly in 1964, and amended in October 2000) and the Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997), the basic ethical principles referred as principlism that should be followed in genomics test/research and services are:

2.5.1 Autonomy

The concept of autonomy is derived from two Greek words – *autos* ("self") and *nomos* ("rule," "governance," or "law"). It was originally used to denote the self-rule or self-governance of independent city-states(Beauchamp & Childress, 2013). The ethical principle of autonomy (a norm of respecting the decision-making capacities of autonomous persons) holds that the choice

of participation in research is autonomous, voluntary and based on informed consent; and persons or groups with diminished autonomy (a person is said to have a diminished autonomy when he/she, at least in some respects, is controlled by other people, or when the person in question is incapable of deliberating or acting on the basis of his/her own plans. For instance, institutionalized persons such as prisoners or mentally retarded may have diminished autonomy) should be given appropriate protection. Thus, research participants:

> should be treated as autonomous agents who have the right to decide whether or not they will like to participate in a research [for instance, genomics research/tests, and the] … rights of persons with diminished capacity such as old age, physical impairment, lack of education, incarceration, debilitating financial and other social circumstances and mental illness must be protected from harm and risk(University of Ibadan Ethics Policy, 2010).

Identifiable information (clinical, genomics, and the like) of individuals or groups is confidential and should be protected.

A philosophical basis for treating individuals as autonomous agents is clearly seen in the works of Kant. Kant contends that respect for persons is required due to our inherent dignity, which in turn is due to our being rational creatures(Yale Human Subject Research Resource & Education Program, 2006). Being an autonomous person is impossible without one belonging to the community of people who have access to the same sources of autonomy. In as much as being a person matters, belonging to the community of persons must necessarily matter, and the importance of both is what makes it important to act for reasons. Therefore, it is irrational, as Kant argues, to treat any person merely as a means, regardless of any reason whatsoever. Reasons matter because persons matter, and thus, one cannot show his/her regard for reasons by showing disregard for persons(Velleman, 2010).

The concept of autonomy is very important in genomics research/test. This is because, before one can be said to conduct an ethical or acceptable genomics research/test, he/she must allow his/her potential research participants, as autonomous agents, to make decision as to whether or not to participate in the research, and the researcher must as well protect people with diminished autonomy from harm and risk. Freedom to make decision as to whether or not to participate in genomics research/test is part of what it means to have respect for human persons. And as Kant would contend, human persons must never be used as a mere means to the ends of others, but always as ends in themselves. In genomics research/test, a person's moral autonomy is violated if the decisional process is denied, even if the person would have acted in the same way had he/she been given the opportunity to decide.

2.5.2 Justice

The moral principle of justice (a group of norms for distributing benefits, risks and costs fairly) requires that there should be equitable distribution among all segments of the society of both the burden and benefits. Therefore, it is unjust as well as unethical to expose research participants to risk and withhold the benefits of the research from them. According to Belmont Report, "an injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly"(National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Ethical principle of justice also calls for fairness in the distribution of both benefit and risk of research. Moreover, the principle requires inclusion of diverse elements of the population, there should be no discrimination, in genomics tests, against individuals (born or unborn including embryo) or

groups. In genomics tests also, there should be equitable access to information, tests and procedures(Ethical Policies on the Human Genome, 2014).

Just like autonomy, the concept of justice is very significant in genomics research/test. For, it would be unethical to carry out genomics research/test that does not fairly select research participants, or that exposes research subjects to risk and withhold the benefits of the research/test from them. All individuals that are involved in genomics research/test should be treated fairly.

2.5.3 Beneficence

According to Belmont Report, "persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being"(National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Securing the well-being of the research participants falls within the principle of beneficence. The principle of beneficence refers to a moral obligation to act for the benefit of others(Churchchill, 1995). In the context of research, the concept of beneficence requires researchers to work in such a way that research participants stand to benefit from the research they participate. Risks associated with research, for instance, genomics research/test, must be made clear to the research subjects. Health care professionals who conduct genomics tests are expected to carry out reasonable assessment of potential risks and potential benefits before implementation. In addition, the principle of beneficence demands that those who carry out genomics tests be competent enough to conduct the tests and to safeguard the welfare of individuals who participate in the tests to secure their physical, mental and social well-being.

The principle of beneficence incorporates two principles, namely, the principle of positive beneficence and the principle of utility. The principle of positive beneficence requires physicians to do good for others, and also do positive benefit for the society(Beauchamp & Childress, 1979). The principle of utility demands that "in medical practice and research […] risks of harm must constantly be weighed against possible benefits"(Beauchamp & Childress, 1979). In addition, the principle of utility teaches that "we also have a moral duty to weigh and balance possible benefits against possible harms in order to maximize benefits and minimize risks of harm"(Beauchamp & Childress, 1979). The principle of utility is taken as a norm in medical problems because there is a kind of balance between benefit and harm in the principle. In brief, there should be a balance between "possible beneficial actions" and "possible harmful actions"(Beauchamp & Childress, 1979).

In genomics research/test, the ethical principle of beneficence is vital because it would be unethical to put human beings at risk without making efforts to secure their well-being. There should be a reasonable risk and benefit assessment of genomics research/test before research subjects are enrolled in it.

2.5.4 Non-Maleficence

The ethical principle of non-maleficence is of the view that people have obligation not to inflict harm intentionally. Non-maleficence (*Primum non nocere*: above all (or first) do no harm – a norm of avoiding the causation of harm) opines that we should avoid harm. As Beauchamp and Childress put it, the principle of non-maleficence contains the following rules: "do not kill, do not cause pain or suffering to others, do not incapacitate others, do not cause offense to others,

do not deprive others of the goods of life"(Beauchamp & Childress, 2001). The ethical principle of non-maleficence, therefore, advocates that people should treat others with respect and avoid things that could cause harm to them.

In genomics research/test, efforts should be made by genomic service providers to protect their research participants from harm, be it physical, psychological or social harm.

2.6 Risks and Benefits of Genomics Testing

The benefits of genomics research/test cannot be over-emphasized. Genomics research/test has contributed immensely to the knowledge of human health and diseases. Not only that it helps in knowing the present health status of individual who undergoes the test, it also aids in knowing whether or not the person is at risk of a particular disease. The test enables healthcare professionals to determine the type or dose of medication that is best for a certain person. And this is possible through the help of pharmacogenomics, one of the major areas in genomic research that tries to create safer, more effective drugs for individuals based on their genetic makeup(Roses, 2004). Genomic research/test also helps to improve disease classification and generate innovative therapies, targeted more precisely to the molecular mechanisms of disease(Austin, 2004).

The physical risks accompanying genomics research/test are not much, particularly for the test that requires only a blood sample or buccal smear (this is a procedure that samples cells from the inside of the cheek). Many of the risks connected to genomics tests have to do with emotional, social, or financial consequences of the results. People may feel angry, depressed, anxious, or

guilty about their results. In some cases, genomics research/test creates tension within a family because the results can reveal information about other family members in addition to the person who is tested.(Genetics Home Reference, 2014)

More so, the possibility of genomic discrimination in employment or insurance is a thing of serious concern. Some individuals avoid undergoing genomics test due to the fear that they could face genomic discrimination from employers or insurers(Amy Harmon, 2008). Genomics test result, when gets to a wrong hand, could lead to stigmatization. It can also cause serious psychological harm.

2.7 Nature and Limitations of Genomics Testing

Genomics test, in some cases, provides reliable and accurate information on which people can make decisions, while in other cases, it may not be possible to obtain definitive results and thus may leave a person in a state of confusion, grappling with what to do with such results. Human beings, viewed holistically, are far beyond the sum of their genes – their environment is capable of modifying the expression of genomic messages to the body and many factors are not genomic that make human beings who they are(Center for Genetic Education, 2012).

It has been noted that the discovery of a variation in a particular gene may provide some information about the nature of the condition that the person has, will develop or for which they may be at increased risk, but can rarely predict the severity of the condition or the age at which symptoms will first commence and in prenatal testing, the potential for quality of life for the child or the severity of a particular condition(Center for Genetic Education, 2012).

CHAPTER THREE: ETHICAL IMPLICATIONS OF GENOMICS TESTS

It is pertinent to note beforehand that the ethical issues (privacy, confidentiality, discrimination, stigmatization and informed consent) that are being examined in this research are not peculiar to genomics. What is important for this research is that they require special attention in the context of genomics due to the fact that genomics research/test reveals large volume of information, and often generates information that is sensitive to individuals, families, or communities.

More than that, genomics is special because gene-based approaches introduce a new language of "probability" and "susceptibility" to medical care, and furnish information about disorders; that often is of great interest to third parties – families, governments, insurance companies, law enforcement or scientific researchers(World Health Organization, 2013).

3.1 Genomic Privacy

Privacy refers to an individual's right to be free from intrusion or interference by others. Individuals have privacy interests in relation to their bodies, personal information, expressed thoughts and opinions, personal communications with others, and spaces they occupy(Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, 2013.).

Research affects these various domains of privacy in different ways, depending on its objectives and methods. An important aspect of privacy is the right to control information about oneself. The concept of consent is related to the right to privacy. Privacy is respected if an individual has an opportunity to exercise control over personal information by consenting to, or withholding consent for, the collection, use and/or disclosure of information(Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, 2013.).

Paramount in the conduct of genomics studies is concern about protecting the privacy of potentially sensitive genomics information generated from research participants. Privacy concerns arise because many individuals, institutions, and/or organizations have an interest in knowing a person's genomic status, and such knowledge has the potential to result in stigmatization, discrimination, and other adverse effects(Durfy, 2001).

When the word "privacy" is used to label issues that arise in contemporary bioethics and public policy, it generally refers to one of four categories of concern – (1) informational privacy concerns, which is about access to personal information; (2) physical privacy concerns, focuses on the access to persons and personal spaces; (3) decisional privacy concerns is about governmental and other third-party interference with personal choices; and (4) proprietary privacy concerns is about the appropriation and ownership of interests in human personality(King, et al, 2006).

"Genomic privacy" typically refers to informational privacy (informational privacy can be defined as the right of an individual to control access to personal genomic/genetic information), including the confidentiality, anonymity, or secrecy of the data that result from genomics testing and screening(King, et al, 2006).

Presently, genomic privacy concerns range from far beyond informational privacy to concerns about physical, decisional, and proprietary privacy. In brief, issues of physical privacy underlie concerns about genomics testing, screening, or treatment without voluntary and informed consent. Without valid informed consent, these practices constitute unwanted physical contact, compromising interests in bodily integrity and security. Decisional privacy calls for autonomous decision-making by individuals, couples, or families, who use genomic services. A degree of choice regarding genomic counseling, testing, among other things, is requirement of respect for decisional privacy. Lastly, Proprietary privacy is the right an individual has to his/her genetic information. It covers issues that relate to the appropriation of individual's possessory and economic interest in their genes and other putative bodily repositories of personality(King, et al, 2006).

Ethical issue of privacy in genomics research/test should be well considered when conducting genomics research/test so as to avoid harm that could experience by genomics research subjects as a result of the violation of their privacy right.

3.2 Confidentiality

The ethical duty of confidentiality refers to the obligation of an individual or organization to safeguard entrusted information. This ethical duty includes obligations to protect information from unauthorized access, use, disclosure, modification, loss or theft. Fulfilling the ethical duty of confidentiality is essential to the trust relationship between researcher and participant, and to the integrity of the research project(Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, 2013).

When researchers obtain information with a promise of confidentiality, they assume an ethical duty that is central to respect for participants and the integrity of the research project. Breaches of confidentiality may harm the participant, the trust relationship between the researcher and the participant, other individuals or groups, and/or the reputation of the research community. The ethical duty of confidentiality applies to information obtained directly from participants, or from other researchers or organizations that have legal, professional or other obligations to maintain confidentiality(Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, 2013).

As with other areas of clinical medicine or science, confidentiality is important in genomic testing. If anything, the confidentiality of genomic information may need to be guarded even more stringently than in the ordinary case. Genomics tests give an assessment of an individual's inherent risk for disease and disability. This predictive power makes genomics testing particularly liable for misuse(World Health Organization, Genetic Testing, 2014).

Employers and insurance companies have been known to deny individuals essential health care or employment based on knowledge of genomics disposition. This type of discrimination can be socially debilitating and have severe socio-economic consequences. It is important, therefore, to ensure the confidentiality of test results, and to establish legislation permitting only selective access to this information(World Health Organization, Ethical, Legal and Social Implications (ELSI) of Human Genomics, 2014).

Genomic information can have important implications not only for the person who is tested, but also for his/her relatives. Respecting a patient's confidentiality by not disclosing the

results of a genomics test to third parties can therefore conflict with the well-being of family members, who could benefit from this knowledge. Finding the right balance between the patient's privacy and confidentiality of his/her genomics/genetic information, and what is in the best interests of family members, is an ongoing ethical and social challenge.(World Health Organization, Ethical, Legal and Social Implications (ELSI) of Human Genomics, 2014)

The concept of confidentiality is vital in genomics research/test due to the fact that genomics research/test reveals a lot of information that when gets to a wrong hand, could lead to stigmatization and discrimination, and thereby causing harm to the research subjects.

3.3 Stigmatization and Discrimination

Stigma is a degrading and debasing attitude of the society that discredits a person or a group because of an attribute (such as an illness, deformity, color, nationality, religion, to mention but these). The resulting coping behavior of affected person results in internalized stigma. This perceived or internalized stigma by the discredited person is equally destructive whether or not actual discrimination occurs. Stigma destroys a person's dignity; marginalizes affected individuals; violates basic human rights; markedly diminishes the chances of a stigmatized person of achieving full potential; and seriously hampers pursuit of happiness and contentment(Howard University, 2014).

On another note, discrimination can be defined as an unfair treatment given to individual as a result of his/her membership in a particular group of people or him/her having a particular characteristic. Some people have fixed ideas about groups of people who are different from

themselves. These fixed ideas, if care is not taken, can lead people to discriminate against those people who belong to the different groups(Anti-Discrimination Board of New South Wales, 2014).

Genomic discrimination has been defined as the denial of rights, privileges, opportunities, or other adverse treatment based solely on genomic information, including family history or genomics test results(Gostin L., 1991). This definition is inclusive of a broad range of discriminatory activities that may arise in the interpersonal dealings of individuals in their daily lives and comports with the experience of familial discrimination(Treloar S. et al., 2004) or other social stigma and discrimination that is a feature of life experiences for some people who have family members with genomics condition such as Huntington Disease(Erwin, et al., 2010).

Knowledge of genomics risks can lead to potential social and psychological consequences for the individual. Socially, knowledge from genomics tests may lead to stigmatization and discrimination within the community. Further, knowledge of test results may lead to the marginalization of the individual from mainstream society by virtue of the health risks identified(World Health Organization, Genetic Testing, 2014).

Discrimination can be in the form of denial of health insurance, employment or simply social acceptance. In particular, knowledge of risk of disease may be used by health insurance providers and employers to deny individuals employment, benefits and allowances and medical coverage or health insurance. This is especially worrisome in communities that rely heavily on private insurance systems as a source of funding for necessary medical treatments(World Health Organization, Genetic Testing, 2014).

Genomic discrimination and stigmatization have been a serious problem in genomics research/test. Genomic information could unjustly be used to discriminate against or stigmatize individuals on the job. For instance, people may be denied jobs or benefits due to the fact that they have particular genetic traits, even when the trait has nothing to do with their performance on the job(National Human Genome Research Institute, Genetic Information and the Workplace, 1998). Therefore, there should be adequate protection of genomic information to prevent it from getting to a wrong hand.

3.4 Informed Consent

Informed consent is the process by which the health care provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment(Appelbaum, 2007). It originates from the legal and ethical right the patient has to direct what happens to his/her body and from the ethical duty of the physician to involve the patient in his/her health care(De Bord, 2014).

Some scholars have identified at least three distinct senses in which the concept of informed consent can be looked at. The first is the policy-oriented conception of informed consent. The second is the philosophical conception (informed consent as autonomous authorization) of informed consent. And the third is shared decision-making.

The first sense of informed consent, the policy-oriented conception of informed consent, has to do with "legally or institutionally *effective* … authorization from a patient or subject. Such authorization is 'effective' because it has been obtained through procedures that satisfy the rules and requirements defining a specific institutional practice in health care or in research".(Faden & Beauchamp, 1986) The rules and requirements mentioned here are very important because in the

absence of them, the actions would have a different meaning. Moreover, it is the presence of the provisions of laws and institutional policies that the statement of a patient, for instance, “Okay, I agree to have the Caesarean section” has the effect of authorizing the physician to commence the operation(Faden & Beauchamp, 1986).

The second sense of informed consent, the philosophical conception (informed consent as autonomous authorization) of informed consent, refers to “an autonomous action undertaken by a subject or a patient that authorizes a professional either to involve the subject in research or to initiate a medical plan for the patient [or both]”(Faden & Beauchamp, 1986). When an individual authorizes another, the implication of that is that he/she has both assumed the responsibility for what he/she has authorized and has transferred to another individual the authority to carry out the action. And this is the reason why one is expected to understand the fact that in authorizing, he/she assumes responsibility for what he/she warrants another to implement(Faden & Beauchamp, 1986).

The third sense of informed consent, the shared decision-making, has to do with some degree of shared decision-making or series of interactions between health care professional and patient or researcher and potential research participant. Patients and research participants often look up to the health care professionals and researchers to adequately inform them in order to enable them to autonomously authorize a course of action.(Berg, et al., 2001) This, probably, is the reason why Psychiatrist Jay Katz and the President’s Commission try to equate informed consent with shared decision-making, the third sense of informed consent(Katz J., 1984)’(President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982). Nevertheless, informed consent is only one aspect of shared decision-

making. Informed consent, in the sense of autonomous authorization, can occur without shared decision-making(Berg, et al., 2001).

These three senses of informed consent, as discussed above, are interrelated. This is because the rules and requirements that constitute informed consent in the institutionalized, policy-oriented sense are made to promote shared decision-making and to enable autonomous authorization. Nonetheless, it is significant to identify the distinctions inherent in these conceptions of informed consent.

A close look at these three conceptions of informed consent shows that sometimes strict adherence to the rules governing informed consent may challenge the dialogue involved in the process of shared decision-making, or may even fail to enable a particular patient to autonomously authorize a treatment plan(Berg, et al., 2001). To put in another way, placing too much emphasis on *sharing* decision may undermine the decisional authority of some patients, for instance, if they over-value maintaining a good relationship and comfortable interaction with their doctors at the expense of expressing their own views. This may eventually lead the patients to be disappointed when they find out that they, not their doctors, are responsible for whatever they authorize their physicians to do. Consequently, patients may want to blame their doctors for choices they later regret. Being fully aware of the fact that in authorizing another to act on one's behalf that the authorizer still bears the responsibility for what is authorized, may help avoid misplacing blame. But in order for one to be responsible for what he/she authorizes, the person must be well-informed and act autonomously(Berg, et al., 2001).

Consistent with the ethical principle of respect for persons(National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979), the goal of informed

consent is to make sure that research participants are aware of the risks and potential benefits of research in order to make a voluntary decision as to whether or not to participate in the research(National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Nevertheless, the traditional conceptions of informed consent have been seriously challenged as a result of the advances in genomics and genetic research, particularly the increasing emergence of large-scale population studies and genomic databases(Caulfield, et al., 2003).

Traditionally, the standards of informed consent, with limited exceptions, demand that potential research participants enter into research voluntarily and with sufficient information concerning the research activity to make an informed decision about participation(Department of Health and Human Services, 2011). In spite of this, the storage and broad sharing of bio-specimens (bio-specimens are samples of material, such as urine, blood, tissue, cells, DNA, RNA, and protein from humans, animals, or plants) and data make it impossible to describe in detail or even to foresee all of the future research for which they might be used at the time they are collected(Amy & Beskow, 2010).

In addition, with the rapid technological advancement, the future risks associated with research using bio-specimens and data are not predictable(Amy & Beskow, 2010). As a result of this, the legal and ethical requirements of informed consent for all future uses of such bio-specimens and date cannot be satisfied at the time they are collected. Even so, most people would agree that stored specimens and data are valuable resources and should be used to advance research if appropriate protections are put in place. Several alternative approaches to consent for genomic and genetic research have been proposed to address this inherent tension(Amy & Beskow, 2010).

All the approaches maintain the view that any research that involves the use of human biological materials has two distinct steps. The first step is the *collection* and *storage* of specimens and data. The second step is the *use* of stored specimens and data for research.

In the first step, specimens and data may be collected for dual purposes. First, they may be collected as part of a primary research study and then kept for other uses. And second, specimens and data may be collected and stored as part of an independent effort to build a "bio-bank" (A bio-bank is an ultra-low temperature freezer or a liquid nitrogen container that stores biological samples (usually human) for research). In both cases, to establish a repository of specimens and/or data intended for future use, which may not be seen as a 'study' in a strict sense, is a research activity(Department of Health and Human Services, 2011). For this reason, such research activity must be in line with research ethics norms, and in the United States, for example, it must fulfill federal regulations pertaining to the protection of human research participants(Department of Health and Human Services, 1980).

In many cases, these federal regulations demand that researchers should obtain approval from Institutional Review Board (IRB), and in addition to this requirement, they are expected to obtain research participants' informed consent specifically for this research activity. In the process of obtaining this informed consent, potential research participants can be given comprehensive information concerning the repository (that is, the collection of stored materials) itself, including details relating to its purpose, procedures, confidentiality protections, risks, and benefits(Amy & Beskow, 2010).

Informed consent is unarguably vital in genomics research/test. This is because it gives potential research subjects an opportunity to make an informed and voluntary choice to participate

or refuse to participate in the research. The absence of it in genomics research/test renders the research/test unethical. As Kant would argue, human persons should not be used as a mere means to an end. Not seeking and obtaining the informed consent of genomics research participants before they are enrolled in the research is tantamount of using them as a mere means to an end, which is unethical.

It is noteworthy that the primary reason behind all these regulations is to ensure adequate protection of research subjects from harm, be it psychological, physical or social harm. It is an evidential fact that research is inevitable for human advancement. However, research must be done in a manner that recognizes and treats human research participants as human beings who have right and dignity that must be protected, and not to treat them like "guinea pigs".

CHAPTER FOUR: ETHICAL IMPLICATIONS OF GENOMICS TESTS: A DEONTOLOGICAL-UTILITARIAN DISCUSSION

Having looked at some of the ethical implications of genomics tests in the previous chapter, we now turn to discuss the ethical implications of genomics tests from the points of view of Kantian deontology and Bentham's utilitarianism.

4.1 A Discussion on Genomic Privacy from the points of view of Kantian deontology and Bentham's utilitarianism

As previously noted, research is unavoidable for human advancement. This makes research a necessary condition for scientific development. Hence, research must be done if one really craves for development in general and scientific development in particular. Nevertheless, it is not every research that is worth conducting. Therefore, for one to conduct an ethical and acceptable research, human research participants must necessarily be treated as human beings, and not like animals with lower status.

A reflection on genomic privacy from the Kantian perspective illustrates that it is unethical to intrude into the privacy of a person regardless of whether or not the intrusion would have good consequences to the greatest number of people in the society. Kant would argue that, in genomic research, to intrude into a person's privacy is tantamount to failure to have respect for the person, which, in line with his ethics, is unethical. It does not matter how many people who may benefit from the intrusion. What matters, as long as Kant is concerned, is that the act of the intrusion treats the person, in Kantian words, "merely as means".

Bentham, on the other hand, would first consider whether or not the intrusion into the person's privacy would maximize utility for the greatest number of people. If the intrusion would maximize utility for the greatest number of people, Bentham would judge the act to be ethical based on the fact that it produces greatest happiness for the greatest number of people.

From the above, one can infer that Kant would strongly maintain that a person has right not to be intruded into his/her privacy. Kant would also argue that infringing on this right would render genomic research/test unethical. On the contrary, Bentham would contend that the intrusion into a person's privacy is not unethical insofar as the intrusion produces greatest happiness for the greatest number of people.

Looking at the conflicting views of Kant and Bentham on genomic privacy from the African perspective, it is clear that the Kantian argument on genomic privacy would be favoured less than Bentham's in Africa. Africa, to start with, is a continent where communalism is the basis of existence in most societies(Zion, 2005). And communitarianism gives consideration to the acts that best promote community interest and values and not the interest of the individual(Jegede, 2009). Moreover, in Africa, "an individual does not exist alone but within a web of social and cultural relationships"(Jegede, 2009). So, from African perspective, intrusion into a person's privacy for the benefit of the whole community would favour Bentham's position/argument most but definitely not completely. This is because, although the right individual has in the African setting is limited, it has been argued that it cannot be overlooked. This explains the reason why in the African setting, decisions are not taken in the absence of the person the decision is being made on(Jegede, 2009). Hence, both utilitarianism and deontology have points in their various claims. Therefore, the strong points of both ethical theories should be harnessed for the good of genomic researchers, research subjects and the African community where the research is being conducted.

4.2 A Discussion on Confidentiality in Genomic Research/Test from the perspectives of Kantian deontology and Bentham's utilitarianism

Confidentiality concerns the obligation of an individual or organization to safeguard entrusted information. This is seen as an obligation due to the harm unauthorized disclosure of the information could cause a person whose information is being disclosed, if the information gets to a wrong hand. In this respect, Kant's position would indicate that it is morally objectionable to disclose a person's genomic information to a third party without first seeking and obtaining approval from the person in question. In judging whether the disclosure of the information gathered on a genomic research subject is right or wrong, Kant would not concentrate on the benefits or good consequences the disclosure of the person's genomic information could have on other persons that are directly or indirectly involved, the focus would be on how best the person would be treated as a person who has rights and dignity to be respected and protected, and who should control what happens to him/her as an autonomous agent.

Nevertheless, it is important to bring to light that Kant is not against the progress of the society, what his ethics kicks against is the idea that a person should be used as a mere means of achieving societal progress. So, to divulge a person's genomic information in order to achieve greatest happiness for the greatest number of the person's family members or society in general, from Kantian perspective, is wrong, as long as the valid informed consent of the person is not sought for and obtained.

Bentham, on the other hand, believes that there is nothing wrong in disclosing a person's genomic information without his/her consent, provided the disclosure would produce greatest happiness for the greatest number of people. In determining whether the disclosure of a person's

genomic information without his/her consent is right or wrong, Bentham's idea focuses on whether the outcome of the disclosure or non-disclosure, will bring about the greatest good for the greatest number of people. If the disclosure is seen to be more favourable than unfavourable to the greatest number of people who are directly or indirectly involved, Bentham would judge the act of the disclosure of the person's genomic information to a third party to be right. What matters most, as long as Bentham is concerned, is the maximum good for the greatest number of people. Apparently, Kant would never subscribe to the Bentham's idea on this and vice versa.

To consider the ethical issue of confidentiality from the African viewpoint where emphasis is not placed on individual autonomy, one can say that if the disclosure of the genomic information would in reality maximize utility for the people of the community, it has to be done. But this would be considered unethical if the person in question is not properly informed, since, in African setting, decision is not taken in the absence of the person the decision is being made on. No doubt, individual autonomy is limited but cannot be disregarded in Africa.

The concept of 'person' in the African culture is somebody who has the 'free will' to make choices(Jegede, 2009). It becomes evident then that genomic research participant has the right not to allow his/her genomic information to be disclosed to the people that may benefit from it. But in African culture, however, a person is considered selfish when he/she thinks about himself/herself alone. That is the reason why African people make every effort to act within the acceptable normative value system to avoid being tagged selfish(Jegede, 2009).

4.3 A Discussion on Genomic Stigmatization and Discrimination from the viewpoints of Kantian deontology and Bentham's utilitarianism

Following from the aforesaid, stigma is a degrading and debasing attitude of the society that discredits a person or a group(Howard University, 2014), while discrimination is an unfair

treatment given to individual(s) due to his/her membership in a particular group of people or as a result of the person having a particular characteristic(Anti-Discrimination Board of New South Wales, 2014). Genomic discrimination is the denial of rights, privileges, opportunities, or other adverse treatments based solely on genomic information, family history or genomic test results(Gostin, 1991).

Stigmatization and discrimination occur, among other reasons, as a result of improper handling of information entrusted to a person or organization, or due to unauthorized disclosure of information to a third party. Kant is against anything that causes harm to each person even when majority of people stand to gain from it. Kant would seriously oppose the view that human persons be denied the rights and dignity accorded to them as persons simply because by so doing, greatest happiness would be enjoyed by the greatest number of people.

In that light, Bentham would ask: what would be the consequences of the disclosure of the person's genomic information to the greatest number of people? If the results are more favourable than unfavourable to the greatest number of people, the act has to be done. The emphasis here is not on the sort of act performed but on the number of people who benefit from the act.

It is evident therefore that Bentham is an act utilitarian who judges act, not in terms of what the act is in itself but in terms of the consequences it has or would have on the majority of people who are directly or indirectly involved in the act itself.

Be that as it may, it is the responsibility of the African community to protect its members from harm or injury. As such, community would not work to promote actions that would discriminate or stigmatize its members, since the "peace of the tree is the peace of the bird"(Jegede, 2009). Herein, the tree refers to the community while the bird connotes the individual

members who rest on it. Moreover, the peace of the individual member is the peace of the community, whereas affliction to one member is affliction to others. A person is a person through others; an injury to one is an injury to others.

4.4 A Discussion on Informed Consent in Genomic Research/Test from the points of view of Kantian deontology and Bentham's utilitarianism

Informed consent is considered to be *sine qua non* (an essential condition – a thing that is absolutely necessary) in research. The goal of it is to make sure that research participants are aware of the risks and potential benefits of research so as to make a voluntary decision as to whether or not to participate in research(National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Research, as noted in the foregoing, must be done if and only if one desires to make advancement in all areas of life. Consequently, research is necessarily important if one really needs to make progress in life. Yet, irrespective of the importance of research, it should be carried out in an ethical manner, making sure that human persons who participate in it are protected from harm.

Kant's doctrine indicates that it is wrong for human persons to be used as a mere means to an end. For Kant, each human person should be treated as a person who has rights and dignity, and acting contrary to this would mean treating the person as a mere means to an end, which, in accordance with Kant's teaching, is wrong or unethical. This gives credence to the fact that Kant's principle is not in tandem with the disclosure of a person's genomic information without his/her consent, even when it is obvious that the disclosure of the information would ensure greatest happiness for the greatest number of people.

As previously mentioned, Kant is not against research. On the contrary, he espouses it; for, he knows the role it plays in human well-being. What Kant really frowns at is the idea that human

persons be used as mere means towards achieving progress in life. Kant's ethics condemns in totality the inclusion of a person in a research under duress or coercion, or without informing him/her that he/she is being enrolled in a research, simply because informing him/her might make the person not to participate in the research. Not to seek and obtain informed consent of a person before he/she is enrolled in a research would be wrong from the Kantian perspective regardless of whether or not the person's participation would guarantee greatest happiness for the greatest number of people. As it is customary with Kant, to determine whether this is morally acceptable or objectionable, he would base his judgement on the act itself – checking whether or not the act violates the rights and dignity accorded to the person as human person. The principle of the greatest happiness for the greatest number of people does not make an action right, insofar as the action treats a person involved as a mere means to an end, Kant would insist.

Concerning the issue of collecting bio-specimens in genomic research/test, Kant would argue that the persons whose samples of material are collected should be comprehensively informed about the present and future researches the samples would be used for. Even if the future researches the samples would be used are not clear at the moment the samples are being collected, Kant would maintain that the persons should be informed that the samples would be used in other researches in the future, if the need arises.

The persons whose samples are collected should be informed of the possible uses of the specimen, whether identifier would be retained or not, and whether the persons would be re-contacted about the new developments or not. Kant would see this information as part of what it means to have respect for human person or treat a person as a person and not as a mere means to an end. From the Kantian perspective, therefore, a valid informed consent of the person intended

to be enrolled in a research should be sought and obtained before he/she is enrolled in the research. He would assert that human person should not be treated as a mere means to an end.

Different from Kant, Bentham would apply the principle of utility in determining whether the inclusion of a person in research without his/her consent is right or wrong. For Bentham, if telling a person lies would make him/her participate in a research that majority of people stand to benefit from, it is ethical as long as the research maximizes utility to the greatest number of people. In judging whether an act is morally wrong or right, therefore, Bentham considers the consequences of the act to the greatest number of people, not the nature of the act itself.

In African culture, although individual autonomy is limited, it is however respected. A person, as mentioned earlier, is somebody who has the 'free will' to make choices. Again, individual is dependent on the community, he/she cannot make decision based on his/her own interest but must think of its effect on the community. This is because, if the decision taken by a person affects him/her negatively, it is the community that will suffer it; for, affliction to one member of the community is affliction to others. So, in the African setting, individual autonomy is not completely subsumed by social autonomy, and in genomics research/test, for instance, it is the individuals, not the community leaders, who take decision (the decision must be for the interest of the community) as to whether or not to participate, even though approval would be sought from the community leaders before the commencement of the research/test in the community. The decision must be for the interest of the community because "when talking about harm or benefit in Africa one is referring to the impact of the study on the community"(Jegede, 2009)

CONCLUSION AND RECOMMENDATIONS

Conclusion

By way of conclusion, let us reiterate the procedures followed in this study. We set out, at the beginning of this research, to examine the ethical implications of genomics test from the perspectives of Kantian deontology and Bentham's utilitarianism. The study has four chapters. The first chapter focused on the general introduction, which covered the background of the study, statement of the problem, aim and objectives of the study, relevance and justification of the study, and method of the study. Chapter two was literature review which examined genomics, history of genomics, main areas of genomics research (human genomics, **b**acteriophage genomics, metagenomics, cyanobacteria genomics, pharmacogenomics), genomics test, ethical principles governing genomics tests (justice, autonomy, beneficence and non-maleficence), and the nature and limitations of genomics tests. Chapter three discussed the ethical implications of genomics tests (privacy, confidentiality, stigmatization and discrimination, and informed consent), and chapter four focused on the analysis of the ethical implications of genomics tests from the viewpoints of Kantian deontology and Bentham's utilitarianism.

One can say, from the foregoing, that ethical theories of deontology and utilitarianism have both strong and weak points. For instance, utilitarianism promotes the greatest good. It teaches that the right course of action is the one that leads to the most happiness and least harm. This makes sense. However, there are many circumstances when maximizing utility would be wrong as was clearly shown in the scenario painted above concerning a surgeon, one healthy patient and five sick and dying patients.

The deontology, on the other hand, provides objective guidelines for making moral decisions, without the need for making lengthy calculation of possible consequences. In addition, it is a humanitarian principle in which all persons are considered to be of equal value and worthy

of protection. Nevertheless, there are situations where deontology will lead to disastrous outcomes. For instance, supposing that unless (Mr. A) violates the deontological duty not to torture an innocent person (Mr. B), about one thousand other innocent persons will die because of a hidden nuclear device. If (Mr. A) is not allowed by deontological morality from torturing (Mr. B), many people would consider that as a *reductio ad absurdum* (reduction to the absurd) of deontology.

The ethical theory of utilitarianism, when applied to genomics research/test, could benefit the family members of a person who undergoes the test or the whole community he/she comes from, but the theory, no doubt, could as well lead to the detriment of the person who partakes in genomics test himself/herself, thereby treating him/her as a mere means to the ends of others.

In our judgment, therefore, the doctrine of utilitarianism should be applied to genomics research/test with great caution so that individual's rights would not be sacrificed for the good of others. The respect for a person's rights and dignity is the first step towards creating happiness for that person who is a bona fide member of a family or community. Sacrificing a person's rights and dignity on the altar of maximization of utility for the greatest number of people, as Kant would contend, is nothing but treating the person simply as a mere means to an end.

While not denigrating this Kantian position, one should acknowledge the fact that the way a person who undergoes genomics test has rights and dignity to be protected and upheld, so his/her family members do have their own rights and dignity. For that reason, there is need to balance, for example, privacy and confidentiality of the person with prevention of harm to others (the duty of care). Philosophically, this balancing can be done by employing both utilitarianism and deontology, such that what is lacking in one theory would be supplied by the other.

Although the person who participates in genomics research/test has rights and dignity to be respected and upheld, he/she nonetheless has family responsibilities and obligations which include dissemination of genomics test results within the family to enable informed decision-making by his/her at-risk relatives. But what should one do when a person tested refuses that genomic service provider should make the test result available to his/her relatives? In the context of this research, the genomic service provider is to employ utilitarianism and deontology. By this, we mean that genomic service provider should get consent of the genomics research/test subject by explaining in clear terms to the person his/her responsibilities and obligations to disseminate his/her genomic information to his/her at-risk relatives to enable their informed decision-making. This should be done most especially when effective and affordable treatment or preventive measure is available for the ailment detected in the test.

In a nutshell, the ethical theories of deontology and utilitarianism should both be employed when looking at the ethical issues that arise from genomics research/test.

Recommendations

In this study, we have examined the ethical implications of genomics tests from the perspectives of Kant's deontology and Bentham's utilitarianism. This examination leads to certain recommendations, which are laid out by way of winding up the whole discussion on the essay.

1. It is recommended that since genomics test reveals a lot of information, both sensitive and non-sensitive, stigmatizing and non-stigmatizing, discriminating and non-discriminating, and so on, its results should be protected with utmost confidentiality to avoid harm one could experience if the test results get to a wrong hand.

2. It is our recommendation that since genomics test is new in Africa and since Africans may not have ready access to interventions that would change the test results if the results show that they are at risk of certain diseases, the genomic service providers, as those who are more knowledgeable in the field of genomics than their research subjects, should try to give adequate counseling to their research participants and advise them appropriately to avoid the test results leaving them in a state of confusion, grappling with what to do with such results.

3. Informed consent, as noted previously, is *sine qua non* in research. Therefore, it is recommended that before potential research subjects are enrolled in genomics research/test, they should be adequately or comprehensively informed about the risks and benefits of the research/test to enable them make informed decision as to whether or not to participate in it. Genomic researchers should also be monitored to ensure that the manner in which they conduct genomics research/test corresponds with the promise(s) made by them to the research participants to avoid using the research subjects as a mere means to an end.

4. It is recommended that one should balance the strong points of the two ethical theories – deontology and utilitarianism. For instance, one should balance privacy and confidentiality of a person that undergoes genomics test with prevention of harm to others.

5. It is also recommended that the ethical principles (autonomy, justice, beneficence and non-maleficence) known as principlism that govern genomics research/test should all be considered when carrying out genomics research/test.

6. Finally, experience has shown that sometimes, our moral duties override the consequences of our actions, and at other times, the consequences of our actions override certain moral duties. It is therefore recommended that neither utilitarianism nor deontology should be taken as all-encompassing ethical theory when looking at the ethical issues that emanate from genomics research/test; a complementary approach that brings the two theories to complement each other is recommended for the good of the patients/research participants and care givers/researchers.

REFERENCES

Al-Gwaiz LA & Babay, H. H., 2007. The diagnostic value of absolute neutrophil count, band count and morphological changes of neutrophils in predicting bacterial infections. *Med Princ Pract.,* 16 (5): 344–347. doi:10.1159/000104806. PMID 17709921.

AMY HARMON February 24, 2008. Insurance Fears Lead Many to Shun DNA Tests. *The New York Times.*

Amy L. McGuire & Laura M. Beskow, Informed consent in genomics and genetic research. *Annu Rev Genomics Hum Genet. Sep 22, 2010; 11: 361–381.*

Anti-Discrimination Board of New South Wales, 2014. Available: http://www.antidiscrimination.lawlink.nsw.gov.au/adb/adb1_antidiscriminationlaw.html [Accessed 6/30 2014].

Appelbaum PS., 2007; 357: 1834-1840. Assessment of patient's competence to consent to treatment. *New England Journal of Medicine*.

Austin CP. The impact of the completed human genome sequence on the development of novel therapeutics for human disease. Annu Rev Med 55:1-13. 2004.

Bruce N. Waller 2005. *Consider Ethics: Theory, Readings, and Contemporary Issues.* New York: Pearson Longman, p.23.

Caulfield T., Upshur R.E. & Daar A., DNA databanks and consent: a suggested policy option involving an authorization model. *BMC Med Ethics. 2003;4:E1.*

Center for Genetic Education, 2012. Some Ethical Issues in Human Genetic and Genomics. *Fact Sheet 23*.

Center for Genomics and Public Health. 2011; Available: http://depts.washington.edu/cgph/GenomicsGenetics.htm.

Centers for Disease Control and Preventions. Available: http://www.cdc.gov/newbornscreening/ [Accessed 10/14 2014].

Cheryl Erwin, Janet K. Williams, Andrew R. Juhl, Michelle Mengeling, James A. Mills, Yvonne Bombard, Michael R. Hayden, Kimberly Quaid, Ira Shoulson, Sandra Taylor, Jane S. Paulsen & et al, Jul 2010; 153B(5): 1081–1093. . Perception, Experience, and Response to Genetic Discrimination in Huntington Disease: The International RESPOND-HD Study. *Am J Med Genet B Neuropsychiatr Genet*.

David Velleman 2010. A Brief Introduction to Katian Ethics. *In:* By John Perry, Michael Bratman & & John Martin Fischer (eds.) *Introduction to Philosophy: Classical and Contemporary Readings.* 5th ed. New York Oxford University Press.521-537.

Davis, N. 1991. Contemporary Deontology. *In:* Singer, P. (ed.) *Blackwell Companions of Philosophy: A Companion to Ethics.* USA: Blackwell Publishing Ltd.206-207.

Department of Health and Human Services, May 1980. Code of federal regulations, title 21: Food and Drug, Chapter 1 - Food and Drug Administration, Part 50: Protection of human subjects.

Department of Health and Human Services, Revised October 1, 2011 Code of Federal Regulations, Title 45: Public Welfare, Part 46: Protection of human subjects, Subpart A: Basic HHS Policy for Protection of Human Research Subjects.

Driver Julia 2007. *Ethics: The Fundamentals.* Blackwell, p. 97.

The Encyclopedia of Philosophy, Vol. 7 1967. *In:* Edwards, P. (ed.) *Utilitarianism.* New York: Macmillan Publishing Co., Inc. & The Free Press.

Ethical Policies on the Human Genome, Genetic Research & and Services. Available: http://dbtindia.nic.in/uniquepage.asp?id_pk=113 [Accessed 3/28 2014].

Ettorre Elizabeth, Reproductive Genetics, Gender and the Body: 'Please Doctor, may I have a Normal Baby? *Sociology, 2000;34(3):403-20. English.*

Faden R.R. & and Beauchamp T.L. 1986, p. 278. *A history and theory of informed consent.* New York: Oxford University Press.

Faden R.R. & and Beauchamp T.L. 1986, p. 280. *A History and Theory of Informed Consent.* New York: Oxford University Press.

Fiers W, Min Jou W, Haegeman G, Ysebaert M. Nucleotide sequence of the gene coding for the bacteriophage ms2 coat protein, . Nature 237 (5350): 82–88 Bibcode:1972Natur23782J doi:101038/237082a0 PMID 4555447. 1972.

Fried C. 1978. *Right and Wrong.* Cambrigde Mass: Havard University Press.

Genetics Home Reference: Your Guide to Understanding Genetics Conditions, 2014. Available: http://ghr.nlm.nih.gov/handbook/testing%3Fshow=all [Accessed 4/7 2014].

Genomics and Global Health: A Report of the Genomics Working Group of the Science and Technology Task Force of the United Nations Millennium Project 2004. Toronto: University of Toronto Joint Centre for Bioethics.

Genomics in Theory and Practice. 2012. Available: http://www.genomic.org.uk/genomic-genetic-testing.html [Accessed 03 - 04 2014].

Gostin L., 1991;17(1–2):109–144. Genetic discrimination: The use of genetically based diagnostic and prognostic tests by employers and insurers. *Am J Law Med*.

Gregory E. Pence 2007, p. 6. *The Elements of bioethics.* New York: McGraw-Hill.

Gregory E. Pence 2007, p. 7. *The elements of bioethics.* New York: McGraw-Hill.

Gregory E. Pence 2007, pp. 7-8. *The elements of bioethics.* New York: McGraw-Hill.

GUTTMACHER, A. E. & COLLINS, F. S., 2002 Genomic Medicine - A Primer. *New England Journal of Medicine,*: 347, 1512-1520.

Hoff, A. O., Cote, G. J. & Gagel, R. F., 2000. Multiple Endocrine Neoplasias. *Annual Review of Physiology,* 62.1: 377-411.

Howard University. 2014. *What is Stigma?* [Online]. Washington, DC: Howard University. Available: http://www.whocanyoutell.org/what-is-stigma/ [Accessed 4/14 2014,].

Hunter DJ, Muin JK & Jeffrey, M. D., 2008. Letting the genome out of the bottle. *New England Journal of Medicine 358:105-107*.

Immanuel Kant, Fundamental principles of the metaphysic of morals. [1785] , Trans. by Thomas Kingsmill Abbott, project gutenberg, p 23. 2013.

Immanuel Kant *Groundwork for the metaphysics of morals. [1785] Trans. By Allen W. Wood. London: Yale University Press, 2002, p. 16.*

Immanuel Kant, Groundwork for the Metaphysics of Morals. [1785]. "First Section: Transition from the Common Rational Moral Cognition to Philosophical Moral Cognition", Trans. By Allen W. Wood. London: Yale University Press, 2002.

Immanuel Kant 1785. *Groundwork of the Metaphysic of Morals, Trans. By H.J. Paton.* New York: Harper and Row, 1965.

Immanuel Kant 1949. On a Supposed Right to Lie from Altruistic Motives [1797] *In:* Lewis White Beck (ed.) *Critique of Practical Reason and Other Writings in Moral Philosophy.* Chicago: University of Chicago Press 348.

Immanuel Kant, 2002. Groundwork for the metaphysics of morals. [1785] trans. By allen w. Wood. London: Yale university press.

Iowa Institute of Human Genetics. Available: http://www.medicine.uiowa.edu/humangenetics/testing/patients/ [Accessed 3/7 2014].

James P. Evans, Cécile Skrzynia & Wylie Burke, The complexities of predictive genetic testing. *BMJ. Apr 28, 2001; 322(7293): 1052–1056 PMCID: PMC1120190*.

Jegede Samuel Ayodele. African Ethics, Health Care Research and Community and Individual Participation. Journal of Asian and African Studies (JAAS). 2009. SAGE Publications.

Jeremy Bentham 1789. *An Introduction to the Principles of Morals and Legislation.* London: Cambridge University Press, p.1.

Jessica De Bord. 2014. *Informed Consent* [Online]. University of Washington School of Medicine Available: https://depts.washington.edu/bioethx/topics/consent.html.

Jessica W. Berg, Paul S. Appelbaum, Charles W. Lidz & and Lisa S. Parker 2001, p. 17. *Informed Conset: Legal Theory and Clinical Practice.* New York: Oxford University Press.

Jo Handelsman. Metagenomics and microbial communities. Encyclopedia of Life Sciences,2007. p. 1.

Juengst, E. T. 2004. Concepts of Disease after Human Genome Project. *Health, Disease and Illness: Concepts in Medicine.* Washington DC.: Georgetown University Press. 24:248.

Kailos Genetics. *Talking to your patients about personalized medicine,* 2013 [Online]. Available: http://www.kailosgenetics.com/pharmacogenetic-testing/talking-to-your-patients-about-pharmocogenetics/ [Accessed 3/20 2014].

Katz J. 1984. *The silent world of doctor and patient.* New York: Free Press.

L. R. Churchchill 1995. Beneficence. *In:* Reich, W. T. (ed.) *Encyclopedia of Bioethics.* New York: Simon and Schuster Macmillan.

Lawrence M. Hinman. *Utilitarianism: An Introduction* [Online]. Available: http://ethics.sandiego.edu/presentations/AppliedEthics/Theory/Utilitarianism.pdf [Accessed 6/28 2014].

Michael Lacewing. *Utilitarianism* [Online]. Routledge: Taylor and Francis Group Available: http://cw.routledge.com/textbooks/alevelphilosophy/data/A2/Moral/Utilitarianism.pdf [Accessed 26/6 2014].

Molina B Dayal, Ioanna Athanasiadis, Francisco Talavera & et al, 2013. *Preimplantation Genetic Diagnosis,* [Online]. Available: http://emedicine.medscape.com/article/273415-overview [Accessed 3/14 2014].

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Washington, DC: Dep. of Health Educ. Welfare, April 18, 1979.

National Human Genome Research Institute, 2006.

National Human Genome Research Institute, Genetic Information and the Workplace, 1998.

Olson, R. G. 1967. The Encyclopedia of Philosophy, Vol. 1. *In:* Edwards, P. (ed.) *Deontological Ethics.* New York: Macmillan Publishing Co., Inc. & The Free Press.

Patricia A. King & et al 2006, p. 82. *Law, Medicine and Ethics.* New York: Foundation Press.

Patricia A. King & et al 2006, p. 83. *Law, medicine and ethics.* New York: Foundation Press.

Patricia King & et all 2006, p. 15. *Law, medicine and ethics.* New York: Foundation Press.

Patricia King & et all 2006, p. 16. *Law, Medicine and Ethics.* New York: Foundation Press.

Pevsner Jonathan. Bioinformatics and functional genomics. 2nd ed. Hoboken, N.J: Wiley-Blackwell. ISBN 9780470085851;2009.

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research 1982. *Making Health Care Decisions. Volume 1.* Washington D.C.: U.S. Government Printing Office.

Richard B. Brandt 1992 *Morality, Utilitarianism, and Rights,.* New York: Cambridge University Press, p. 197.

Robert M. Davison, 2002, P. 2. Ethics and Research Methods: Proceedings of the 35th Hawaii International Conference on System Sciences.

Roses AD. Pharmacogenetics and drug development: The path to safer and more effective drugs. Nat Rev Genet 5:645-656. 2004.

Shahmirzadi, L., Chao, E. C., Palmaer, E., Parra, M. C., Tang, S. & Gonzalez, K. D. F., 2013. Patient decisions for disclosure of secondary findings among the first 200 individuals undergoing clinical diagnostic exome sequencing. *Genetics in Medicine*.

Sharon J. Durfy 2001. Ethical and Social Issues in Incorporating Genetic Research into Survey Studies. *In:* Caleb E. Finch, James W. Vaupel & Kevin Kinsella (eds.) *Cells and Surveys: Should Biological Measures Be Included in Social Science Research?* Washington (DC): National Academies Press (US).

Sissela Bok 1988. Kant's Argument in support of the maxim: Do what is right though the world should perish. *In:* Rosenthal, D. M. & Shedadi, F. (eds.) *Applied ethics and ethical theory.* Salt Lake City, Utah: University of Utah Press.192.

Spinello, R. A. 1995. *Ethical Aspects of Information Technology.* Englewood Cliffs, NJ: Prentice Hall.

Springer. Human genomics. 2014.

The Nuriev's Clinic, Prenatal Diagnosis, 2012. Available: http://www.nnplus.ru/en/genetics/ [Accessed 3/6 2014].

T. L. Beauchamp & & J. F. Childress 1979, p. 143. *Principles of biomedical ethics.* New York: Oxford University Press.

T. L. Beauchamp & & J. F. Childress 1979, p. 144. *Principles of biomedical ethics.* New York: Oxford University Press.

T. L. Beauchamp & & J. F. Childress 1979, p. 136. *Principles of Biomedical Ethics.* New York: Oxford University Press.

T. L. Beauchamp & & J. F. Childress 2001, p. 117. *Principles of Biomedical Ethics.* New York: Oxford University Press, Inc.

T. L. Beauchamp & & J. F. Childress 2013, p. 101. *Principles of Biomedical Ethics.* New York: Oxford University Press, Inc.

Treloar S., Taylor S., Otlowski M., Barlow-Stewart K., Stranger M. & Chenoweth K., 2004;7(4):161–168. Methodological considerations in the study of genetic discrimination. *Community Genet*.

Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans & 2nd edition, 2010, Modified April 15, 2013.

University of Ibadan, Ibadan & Nigeria 2010, p. 30. *Ethics Policy*. Ibadan: University of Ibadan Ethics Committee.

Verma IM & Weitzman MD, Gene therapy: twenty-first century medicine, Annu Rev Biochem. 2005;74:711-38. *PMID: 15952901 [PubMed - indexed for MEDLINE]*

Walsham, G., 1996. Ethical Theory, Codes of Ethics and Information Systems Practice. *Information Systems Journal, 6, 69-81.*

World Health Organization, 2014. *Genetic Testing* [Online]. Available: http://www.who.int/genomics/elsi/gentesting/en/ [Accessed 3/30 2014].

World Health Organization 15-16 December, 1998. Proposed international guidelines on ethical issues in medical genetics and genetic services: Report of a WHO meeting on ethical issues in medical genetics .Geneva.

World Health Organization, 2002. Genomics and World Health: Report of the Advisory Committee on Health research.

World Health Organization, 2013. Human Genetics Programme.

World Health Organization, 2014. Human Genetics Programme

World Health Organization, 2014. Ethical, Legal and Social Implications (ELSI) of Human Genomics.

World Health Organization, Toronto, Canada, 9-10 April, 2002. Report of WHO Meeting on Collaborating in Medical Genetics.

Yadav SP. The wholeness in suffix -omics, -omes, and the word om. Journal of biomolecular techniques : JBT 18 (5): 277 PMC 2392988 PMID 18166670. 2007.

Yale Human Subject Research Resource & Education Program, 2006 [Online]. Available: http://learn.yale.edu/hsp/module_1/2_respect.asp.

Zion D. Community Without Communitarianism: HIV/AIDS Research, Prevention and Treatment in Australia and developing world. Monash Bioethics Review 24(2): 20-31. 2005.

Zoltan Papp, Changing Public Demand in the Genetic Counseling during the Past Decades. *Donald School Journal of Ultrasound in Obstetrics and Gynecology, April-June 2011;5(2):175-185*.