



**Southern African Traditional Values and Belief Systems
and the Informed Consent Process in Biomedical
Research: Perceptions of the San's Code of Ethics.**

By

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COLLEGE OF HUMANITIES

DECLARATION - PLAGIARISM

I, Francis Fabian Akpa-Inyang declare that

1. The research reported in this thesis, except where otherwise indicated, is my original research.

2. This thesis has not been submitted for any degree or examination at any other university.

3. This thesis does not contain other persons' data, pictures, graphs or other information, unless specifically acknowledged as being sourced from other persons.

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5. This thesis does not contain text, graphics or tables copied and pasted from the Internet, unless specifically acknowledged, and the source being detailed in the thesis and in the References sections.

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ABSTRACT

Aside from development, further reductions in mortality rates in the population require advances in medical technologies, medications and vaccinations. To achieve these advances, medical research has to be undertaken in populations to determine the safety, efficacy and cost effectiveness of these interventions. In order to provide this evidence base, human participants are required in randomised control trails and studies of other designs. Obtaining proper informed consent is crucial to ensuring that we conduct such studies in an ethical manner. The focus of this work will be on the comprehensibility of the concept and its application on the general population of South Africa, taking into account the fact that informed consent advocates for individuality while most Southern African concepts like Ubuntu emphasizes communal living.

Concepts such as “I am because you are and you because I am” highlight the thinking that one’s existence is dependent on the existence of the group at large. With that said, it bring us to the African communitarian ethic, whose interest is on mutual dependence rather than autonomy, therefore influencing collective decision-making process over individual consent. The above evidence suggest that the application of ethical concepts like informed consent in Southern Africa may encounter intractable ethical problems (moral dilemmas) that might be generated by some of the traditional values, practices, rituals and taboos that still govern people’s behaviour and relationships.

This study explored the concept of informed consent in the doctor-patient relationship in the context of Southern African traditional values, taking into account that the communitarian system in Africa and other traditional African belief systems undoubtedly deepens ones connectedness with family, the language and belief in ancestral spirits/witchcraft. Thus there a dilemma in the application of the western principle of medical ethics in the general population in Africa.

Study Design: The application of the qualitative research method with a case study strategy and the incorporation of the inductive research philosophy with a critical postmodern approach contributed to the effectiveness of the research in achieving its objectives

Measures: Individual interviews were conducted. Medical researchers were asked of their experience of implementing informed consent in South African and their perception of the new San code of ethics.

Analysis: the data from the interview was analysed in combination with data available through publications. The research adopted a thematic content analysis of the available data in order to make some evaluations and thereafter, draw inferences.

As a result, it was discovered in the research that bioethics principles and framework in Africa though may take cognizance of the bioethics principles as postulated by Western philosophy but with different approaches and practices. This is because of the difference in understanding of personhood and social interactions existing within the various communities in Africa compared to what is typically adopted in Western communities. Thus, the need for an alternative approach was necessary and Ross' *Prima Facie* duties were adopted in the research as an alternative approach to ethical decision making in the process of implementing informed consent in Africa.

DEDICATION

This dissertation is dedicated to my siblings Peter Akpa-Inyang and Idongesit Akpa-Inynag and all other children in Africa who died due to poor medical principles and practice.

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I am grateful to my participants who were willing to sacrificing their time to share their experiences with me. I have learnt countless lessons while researching this topic and the valuable input from you (my participants) has contributed to the success of my dissertation.

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ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
BREC	Biomedical Research Ethics Committee
CIOMS	Council for International Organisation of Medical Science
FDA	Food and Drugs Administration
HAVEG	HIV/AIDS Vaccines Ethics Group
HIV	Human Immunodeficiency Virus
KZN	KwaZulu-Natal
NBAC	National Bioethics Advisory Commission
UKZN	University of KwaZulu-Natal
UNAIDS	Joint United Nations Programme on HIV/AIDS
USA	United States of America
WHO	World Health Organisation
WMA	World Medical Association

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CHAPTER ONE

GENERAL INTRODUCTION TO THE RESEARCH

1.1. Background of the Research

Besides development, further mortality rates reduction in the population require advances in medical technologies, medications and vaccinations. To achieve these advances, medical research has to be undertaken in populations to determine the safety, efficacy and cost effectiveness of these interventions. In order to provide this evidence base, human participants are required in randomised control trails and studies of other designs. Obtaining proper informed consent is crucial to ensuring that such studies are conducted in an ethical manner (Buckles, et al., 2003; Wiles, et al., 2007). Thus, if this is to be done the process and application of informed consent and its principles need to be reviewed.

The principles of informed consent originated from the view that an individual's autonomy should be respected. Thus, individual consent became the key aim of informed consent activities and processes. According to Bulger (2002: 30), "informed consent is the process in which a patient/participant consents to participate in a research project after being informed of its procedures, risks, and benefits". Ideally, after fully comprehending the information about the project, the patient/participant gives full and conscious consent for the doctor/researcher to continue with the procedure (Escobedo, Guerrero, Lujan, Ramirez, and Serrano 2007). With the above definition, one could conclude that the rules and norms of informed consent in bio-medical ethics are predominantly informed by Western-European medical and moral traditions with major emphasis being placed on the principles of respect for autonomy.

The Western-European concept of autonomy, which advocates for individual respect, may conflict with African cultural values and norms (Beauchamp and Childress, 2001). The concept of advocating for a form of wholeness that comes through one's relationship and connectedness with other people in the society (Murove, 1999; Munyaka, & Motlhabi, 2009) has been termed *Ubuntu* (isiZulu) and *Ukama* (Shona). The underlying premise is that in order to be fully human, one has to be in close relationship with others in the community. This is because your existence is dependent on their existence (you are because others are and

they are because you are). African communitarian ethics focus on the interests of the collective whole, with this collective being typically defined as family and / or community instead of an individual, hence collective decision-making process takes precedence over individual consent. It will be necessary to point out that the community referred to here is not the Western concept of global community but instead it is the community of humanity where the individual sees himself or herself from the eyes of the community. In the light of this argument Menkiti (1984:172), opines that “a crucial distinction thus exists between the African view of man and the view of man found in Western thought: in the African view it is the community which defines the person as person, not some isolated static quality of rationality, will, or memory”. These considerations suggest that practitioners of Western biomedical ethics in Africa may encounter intractable ethical problems (moral dilemmas) that might be generated by some of the traditional values, practices, rituals and taboos that still govern people’s behaviour and relationships (Chukwunke, Umeora, Maduabuchi, & Egbunike, 2014).

Following the above argument, it has been noted that moral dilemmas present a challenge to the traditional Western way of ethical reasoning and may warrant a number of possible solutions that may seem to be equally valid but mutually exclusive or even may seem unsolvable (Connolly 2009). In any case of ethical disagreement or clash one needs an ability to recognise and identify the problem as well as debate it within a wider framework of agreed-upon rules, established principles and an ethically relevant consideration. Thus, the differences in cultural and moral values and seemingly intractable problems within the traditional ethical theories indicate the need to look for an alternative moral approach and becomes of vital importance in this study (Brody, 2003).

The focus of this work will be to explore the perception of medical researchers in University of KwaZulu-Natal concerning the comprehensibility of informed consent and its application on the general population of South Africa. This will be done taking into account the fact that informed consent advocates for individuality while most South African concepts like *Ubuntu* emphasizes communal living. The San people recently developed their code of ethics and this was motivated by the fact that a lot of research has been done without obtaining proper consent from the San Leaders (Daley 2017). This study will explore the concept of informed consent in the doctor-patient/researcher and research participant relationship in the context of

African traditional values, considering that the communitarian system in Africa and other traditional African belief systems undoubtedly deepens ones connectedness with family, the language and belief in ancestral spirits/witchcraft. Thus, there might be a conflict in the application of the Western principle of medical ethics in the general population in Africa.

1.2. Research Problem

The principle of bio-medical ethics, looking at informed consent, puts emphasis on the individual's autonomy and it is predominantly propelled by the Western-European medical and moral traditions which renders the African traditions and values underrepresented in the practice of medical ethics. This is because African traditions and values advocate more of communitarianism than individualism. The deep rooted understanding of community in African Societies makes it obvious that the principle of individual autonomy in informed consent collapses in its application to the general population of Africa. As analysed above, African communitarian ethics focuses on the interests of family, community and society instead of the individual. Thus, there might be a conflict in the application of the Western principle of medical ethics in the general population in Africa. This conflict is what the study intends to explore.

1.3. Research Proposition

There is a conflict in the application of the Western principle of medical ethics in the general population in Africa.

1.4. Aim and Rationale of the Study

The aim of this research is to analyse the ethical dilemmas of informed consent in doctor-patient and researcher – research participant relationship in the context of traditional African values. It will specifically examine the conflicts that occur in this relationship through the practice of Western concepts of biomedical ethics in Africa. It aims at ascertaining a possible way of implementing the principle of informed consent in the context of African bio-medical

ethics without undermining the traditional value and belief systems using Ross' pluralist theory specifically, *Prima Facie* duties¹ (Ross, 1930).

This study is motivated by the sub-optimal level of poor medical practice in Africa and the challenges that undoubtedly hinder the growth of biomedical ethics in Africa (Ross 1930). These challenges are based on the inability to synchronize African traditional values and belief systems with the principle of biomedical ethics. This study aims at proposing a possible way of synchronizing biomedical ethics principles and African traditional values and beliefs systems.

1.5. Research Questions and Objectives

1.5.1. Key Research Question

- What guiding principles would biomedical researchers be prepared to adopt in an African context to ensure that research could be conducted without undermining traditional values and beliefs?

1.5.2. Research Sub-Question

- What is informed consent?
- What are the perceptions of medical researchers in UKZN concerning the San code of ethics?
- What are the conflicts and limitation in the application of informed consent to the general population of Africa and how can it be approached?
- Is it possible to reconcile the concept of informed consent with the traditional African values and norms of behaviour taking the San code of ethics as case?
- What is the most suitable method for the recognition of arising moral conflicts and controversies and their resolution with respect to traditional values and beliefs?

¹Ross argued that "*Prima Facie* suggests in this approach that one is speaking only of appearance which a moral situation presents at first sight, and which may turn out to be illusory, whereas what he is speaking of is an objective fact involved in the nature of the situation or more strictly in an element of its nature, though not as duty proper does, arising from its whole nature" (1930:20). This introduces us to the seven *Prima Facie* duties which are fidelity, reparation, gratitude, justice, self-improvement, non-maleficence, and beneficence, (Ross 1930).

1.5.3. The objectives of this research are:

- To explore the understandings of the nature of the principle of informed consent among biomedical researchers.
- To explore the possible conflicts that will arise in the application of the principle of medical ethics to the general population in Africa.
- To determine the reasons and grounds for conflicts and controversies that its application can engender in the context of African traditional value and belief systems.
- To argue for the use of an alternative approach to explore the concept of informed consent in doctor-patient relationships in Africa.

1.6. Structure of the Research

The research is divided into five chapters as follows:

Chapter One gives an overview of the research: background/introduction and statement of research problem, research objectives and questions, aim and rationale of the study, research methodology: research limitation and research proposition.

Chapter Two gives a survey of the existing literature on informed consent and its element placing more emphasis on the element/principle of autonomy. The second part of this chapter explores the literature on African values and belief systems.

Chapter Three will present deeper on the research methodology.

Chapter Four gives an analysis of the effect of the application of the principle element of informed consent to the general population of Africa. It explores the relationship between the Western principle of autonomy and African concept of communitarianism. Finally, using the data from interviews and the San code of ethics as the major case, this chapter will explore the possibility of implementing the principle of informed consent in the context of African biomedical ethics without undermining the traditional value and belief systems.

Chapter Five presents the summary of the whole argument in the thesis and conclusion of the study. This chapter also presents policy recommendation based on the research findings as well as suggestion for future research.

CHAPTER TWO

LITERATURE REVIEW AND THE IDENTIFICATION OF A THEORETICAL/CONCEPTUAL FRAMEWORK FOR THE THESIS INFORMED CONSENT AND CULTURAL DIVERSITY:

2.1. Clarifying Goals and Setting Objectives

In this section, this research will examine the concept of informed consent in biomedical ethics (both in research and patient/doctor relationship); to ascertain its applicability in the context of African values and belief systems. With the Western world Emphasis on individualistic ways of life and individual autonomy, it will be right to postulate that it is not possible to apply the concept of informed consent in the context of Africa: or if it is possible, serious caution needs to be taken into consideration with a healthy dose of cultural sensitivity and awareness (Dein, & Bhui, 2005; Faden & Beauchamp, 1986). According to Faden and Beauchamp (1986), respect for autonomy is the most frequently recognised moral principle in the literature on informed consent. It is conceived as a principle rooted in the liberal Western tradition of the importance of individual freedom and choice, both for political life and for personal development. Whereas Africa is a diverse and multicultural continent, thus, there is a need to recognize cultural diversity and also respect people's identities and diversity of their values (Appiah, 2004).

If those are not dealt with, there is a danger of misrecognition which will be disrespectful and harmful to the research subject and patient. Before I go deep into the argument I would like to first explain the concept of informed consent: examine how it has evolved based on the underlying values and beliefs of researchers and then compare and contrast them with African values, beliefs using the existing literature in the field. First, I will start by showing the relationship between biomedical principles and informed consent.

2.2. Principles of Bioethics

2.2.1. Autonomy

Personal autonomy has been a prodigious part of medical and contemporary research especially when it comes to obtaining consent. It refers to “self-governance, and self-rule that

is free from both controlling interference by others and from limitations, such as inadequate understanding that prevents meaningful choice” (Beauchamp & Childress, 2001: 58).

According to Beauchamp and Childress, the principle of respect for autonomy can be seen in two ways: negative obligation and positive obligation. As negative obligation, they argue that autonomous actions should not be subjected to “controlling constraints by others” and as positive obligation, this principle requires “respectful treatment in disclosing information and fostering autonomous decision-making” (Beauchamp & Childress 2001:64).

In comparison to other principles, it will be interesting to note that in the 5th edition of the *principle of biomedical ethics*, Beauchamp & Childress (2001) started the opening discussion on the principle of autonomy although they struggled to argue that their order of presentation does not imply that this principle has priority over all other principles. They assert that the criticism laid on the grounds that the principle of autonomy overrides all other moral considerations is a misguided criticism therefore they firmly deny the above mentioned critique (Beauchamp & Childress 2001).

2.2.2. Justice

The principle of justice concerns itself with how social benefits and burdens should be distributed. In the context of health research, justice concerns itself with sharing the risk and benefit of the research equally and ensuring that people are treated equally and fairly. It also looks at the right of people to equitable access to participation in research studies as well as medical treatment and to the benefits that may accrue during and afterwards. This can be linked to the general concept of justice. For instance the general concept of justice looks at questions like: is it fair that two patients, otherwise similarly situated are treated disparately by the healthcare system because one is affluent and the other is indigent? Between two otherwise similarly situated patients in need of a liver transplant, who should receive the one organ that is available - the recovering alcoholic who has been sober for one year or the patient dying of biliary atresia? (Surman, 1991).

The concept of formal justice is common to all theories of justice and it attributed to Aristotle who opined that justice requires that equals be treated equally and those that are unequal be treated unequally, but in proportion to their relevant inequality. In addition, Aristotle's formal theory of distributive justice makes the distinction between vertical and horizontal equity: horizontal equity refers to equity between people with the same health care needs,

whilst vertical equity refers to those with unequal needs should receive different or unequal health care. In fact, they should receive more resources etc. to make it possible for them to catch up (Beauchamp and Childress 2001:228). The question that will arise from this assertion which this research will like to acknowledge as it will contribute to the argument in this research is how does one determine equality and inequality objectively?

2.2.3. Non-maleficence

The Hippocratic imperative to physicians, articulates that physicians should “bring benefit and no harm”. This codes expresses the principle of non-maleficence and beneficence (bring benefit) (Jonsen, Siegler, & Winslade 2006:18).

The principle of non-maleficence focuses on the duty that refrain the physician from causing harm to the patient/research participant. It underlies the medical maxim *primum non nocere* which translates to “above all (or first of all) do no harm” (Beauchamp & Childress 2001:113). This principle was initiated by Ross as a duty that moral agents owe to each other. Ross (1930) argued that the duty of non-maleficence should advocate that no harm should be done nor allowed to happen to an individual. It should also promote protection of the interest and happiness of the other persons and of society at large. This shows the link between the principle of non-maleficence and the principle of beneficence to put it in the words of David Thomasma (1980, p. 6) “they are more like two side of the same coin. They represent the risk sides of a risk benefit analysis”. That is why this principle is usually addressed in the disclosure of the risks associated with being a participant in a clinical research project.

2.2.4. Beneficence

The common morality requires that one contribute to other’s welfare, perhaps as an embodiment of the golden rule (Lawrence 2007). According to Beauchamp and Childress (2001), there are two principles of beneficence, these are positive and utility. The principle of positive beneficence advocates that moral agents provide benefit, while the principle of utility requires that moral agents weigh benefits and deficits to produce the best result. As mentioned above under the section on non-maleficence, beneficence deals with the issue of a risk benefit analysis also, with non-maleficence representing the deficit/risk side of the equation and beneficence representing the benefit/asset side of the equation.

The problem that arises here and also with the other three principles is the level of measurement, this is because these principles in most cases cannot be objectively followed. For instance in the case of beneficence and non-maleficence, it is not easy to determine how much benefit a moral agent should provide, the basis of weighing that benefit against risk and then what it means to act accordingly. The four principles as a method of ethics gives only the moral agent, the responsibility of determining the good in a specific situation and also the responsibility of weighing that good against the risk of specific actions (Lawrence 2007).

The practice of beneficence is challenged by the respect for autonomy in the above presentation. It is not possible to act without the permission and consent of a free moral agent. Since the idea of 'good' is subjective in the case of the four principles and determining good is a personal decision and the good that a patient may determine can often differ from that of a physician or researcher because of the dichotomy in conceptual and traditional understanding of the case at hand. It is for this reason that Engelhardt suggested that in a situation like this, the principle of permission should be privileged. He argued that "authority for actions involving others in a secular pluralistic is derived from their permission" (Beauchamp and Childress 2001:122). As it is difficult to define what is objectively good on anything, it is easy to argue with Engelhardt that all ethical decisions should flow first from the principle of permission, or as Beauchamp and Childress put it, respect for autonomy.

Furthermore, Feinberg (1986) notes that autonomy minimally requires the ability to decide for the self: free from the control of others and with sufficient level of understanding as to provide for meaningful choice. To be autonomous requires a person to have the capacity to deliberate a course of action, and to put that plan in action (Lawrence 2001). This creates a problem in clinical research as this is not applicable to every person and culture and as it has also become the core factor that influences the provision of informed consent with its need for competence, disclosure, comprehension and voluntariness. Informed consent is one of the key concepts in this research hence in the next section, the researcher will look to explore more on the concepts.

2.3. Informed Consent

It is observed that the practice of informed consent is an ethical norm in contemporary biomedical ethics. According to Manson and O'Neil(2007), informed consent is a central

concept in contemporary biomedical ethics and is seen widely as fundamental to medical and research ethics. Maclean defines consent as “a voluntary unconcerned decision made by a sufficiently competent and autonomous person on the basis of adequate information and deliberation, to accept rather than reject some proposed course of action that will affect him or her” (2009:111-112). According to Bulger, informed consent is designed to give every participant the liberty to decide whether to accept or refuse the recommended medical treatment (2002). “It is to promote the rights of a participant as autonomous beings to ensure that they are treated with justice, beneficence, and respect” (Escobedo, Guerrero, Lujan, Ramirez, and Serrano 2007: 7).

According to Tree (2014), the whole idea of informed consent started after the Second World War. During the Second World War, Nazi physicians in Germany conducted experiments on prisoners without their consent. Some of these experiments resulted in terrible suffering and even death of the research participants. When the war ended the physicians/researchers were tried and convicted by a special tribunal at Nuremburg, Germany. The basis of the judgment is known as the Nuremburg Code, which has served as one of the foundational documents of research ethics. The very first of the ten principles of this Code states: “The voluntary consent of the human subject is absolutely essential.”

While medical research expanded rapidly after World War II, it took a long time before informed consent became a general practice. The World Medical Association (WMA) took the lead in developing ethical guidance for physicians engaged in medical research, and after many years of consultation and deliberation it produced the Declaration of Helsinki in 1964. Informed consent was the main focus of this document, but unlike the Nuremburg Code, it provided for some exceptions to the requirement that individuals must give informed consent if they are to serve as research participants. These exceptions were stated as follows:

- “If at all possible, consistent with patient psychology, the physician should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.”
- “Clinical research on a human being cannot be undertaken without his free consent after he has been informed; if he is legally incompetent, the consent of the legal guardian should be procured.”

These exceptions legitimated the common practice at the time in the USA. of using prisoners, military personnel and institutionalized children and adults as research participants. Although this practice was often abused, there seemed to be no alternative to using children to test vaccines for preventing childhood diseases.

The Declaration of Helsinki has been revised numerous times since 1964, most recently in 2013. Although the wording of the paragraphs dealing with informed consent has been modified, the general principle remains unchanged (Tree 2014).

This shows how important, sensitive, and ever evolving is the issue of informed consent. As awareness of the importance of biomedical ethics expanded outside of the original source countries in North America and Europe, the implementation in new settings still retained in the culture and values of the source settings (Tree 2014). This is why the foundation of biomedical ethics, as well as informed consent, is in Western-European tradition with a very distinct notion of the human person as a rational and autonomous being. These ideas had been consolidated by the enlightenment thinkers, and Kant's categorical imperative is an expression of such beliefs about personhood and a moral foundation for informed consent; it provides an explicit recognition of an idea that treating human beings as objects is immoral. This means not treating human beings as means to an end; instead they are to be treated as ends in themselves (Scruton, 1982). Since treating people as a means to an end is incompatible with the moral obligation of a biomedical professional to do no harm.

However, it seems to be evident that the notion of informed consent has predominantly Western foundations and is a product of Western philosophical beliefs and values and can in a way be harmful when applied to the general population in Africa. In order to determine whether they are directly applicable to African biomedical context requires a brief exposition on African beliefs about the nature of personhood and ensuing from them ethical values and imperatives.

2.4. African Notion of Personhood

According to Menkiti (1984: 172), the African view asserts the ontological primacy and hence the ontological independence of the community. This means that the reality of the person is secondary and derivative. He argued that "as far as Africans are concerned, the reality of the communal world takes precedence over the reality of the individual life histories, whatever these may be".' From the supposed primacy of the reality of the

community, Menkiti infers: first, that in the African view "it is the community which defines the person as person, not some isolated static quality of rationality, will, or memory". " Second, that the African view supports the notion of personhood as acquired through relationship" and third, that "[a]s far as African societies are concerned, personhood is something at which individuals could fail and this happens when one fails to relate or engage fully in the community" (p 173).

Although there are many diverse African cultures, there are commonalities to be found among them in such areas as value systems, beliefs and practices. These areas largely reflect the African worldview. The worldview is greatly influenced by the African communitarian way of life. Specifically Munyaka and Motlhabi (2009) both argue that the most abiding principle of this worldview is known as *Ubuntu* . I will explore this and a other values that contribute to tackling the ethical conflict that arises from the application of Western principle of biomedical ethics. There are a lot of issues surrounding the relationship between doctors and patients or researchers and research participants in Africa. These issues arises from the fact that the principle of biomedical ethics is rooted in the Western-European traditions with major emphasis on individual autonomy, whilst in Africa concepts like *Ubuntu* and *Ukama* and many more advocate for a form of wholeness that comes from one's relatedness and connectedness with others in the society. The key concept in Africa is communitarianism and this is based on the belief that a person's social identity and personality are largely molded by community relationships with a smaller degree of development being placed on the individual. Accordingly, this research would like to explore the concept of *Ubuntu* and *Ukama* in the context of African ethical values and imperatives.

2.5. African Values and Imperatives

2.5.1. The Concept of *Ubuntu*

The word *Ubuntu* or similar meaning words are found in all African languages, although this could not make it immune to misuse and overuse. As it is a strong, meaningful, and loaded concept or value (Munyaka and Motlhabi 2009 :64). As Africans we consider *Ubuntu* as the most important quality of *umuntu* (a human being) (Munyaka and Motlhabi 2009: 64). In this case "*Ubuntu* continues to be a set of institutionalized ideals which guide and direct the patterns of life of Africans. It becomes a notion descriptive of a convergent set of desired goals which all, or at least most, Africans entertain and towards which their activities are directed" (Sogolo 1993: 119). In addition, Broodryk argued that "*Ubuntu* is the whole complex of traditional behaviour which has been developed by the human race and is

successfully learned by each generation..... *Ubuntu* cultural norms have been orally transferred from generation to generation over a long time, and have never been produced as literation or written form” (1997: 22).

If *Ubuntu* is the core central principle in the life of Africans, the question then will be what exactly is *Ubuntu* ? Buntu Mfenyana, a socio-linguist tracing the linguistic concept of *Ubuntu*, establishes that to understand the original meaning of *Ubuntu* we must separate the prefixes and the suffixes that surround the root *NTU* or what to the Sothos is *THO*. The prefix *UBU* refers to the abstract (while) *NTU* is an ancestor who got human society going. He gave us our way of life as human beings (1986: 18). This shows the strong connectedness of Africans with the Supreme Being (God), ancestors and the surroundings.

Ubuntu is commonly defined as a “derivative of the word *untu* meaning a person, a human being” (Munyaka and Motlhabi 2009: 64). According to Chinkanda, the word defines a positive quality supposedly possessed by a person. It is “an internal state of being or the very essence of being human” (1994: 1).

In addition, *Ubuntu* is not only about human acts; it is also about being, “it is a disposition, and it concerns values that contribute to the well-being of others and of the community” (Munyaka and Motlhabi 2009: 65). Munyaka and Motlhabi went on to add that it is then accurate to say that *Ubuntu* is a person’s self-realisation and manifestation as a human being. Having *Ubuntu*, or being human, is identified with having fully one’s human nature and, by implication, in a manner that befits a human being. Thus this makes it possible, in this sense, to denounce a person perceived to lack *Ubuntu* as being inhuman – literally a non-person (2009: 65).

Ubuntu is a way of life which finds its human meaning in expressions recurring across the various African languages in South Africa: *Umntu ngumntu ngabany’ abantu* (Xhosa) or *Motho ke motho ka batho ba babang* (Sotho) or *Umntu ngumuntu ngabantu* (isiZulu) meaning, a person is a person through other persons (Munyaka and Motlhabi 2009: 65). This is one of the tenets of the ethics of *Ubuntu*.

Sparks (1990) believes that this notion, or expression, of mutuality is in the African psyche. As it helps to diffuse the individual ego and makes Africans less prone to acts that do not contribute to the community and its building (1990). It is this feature or quality of *Ubuntu* that distinguishes a human person from other creatures.

The above argument establishes that *Ubuntu* has also a sociological concept. Saule presented this perspective clearly when he asserts that *Ubuntu* represents the kind of human behaviour

that is “inculcated in the individual by the society through established traditional institutions over a period of time” (1996: 83). This definition brings to awareness that *Ubuntu* is attained through socialization. The description also shows where and how the idea of *Ubuntu* originated and how it is achieved and manifested. “Although, there is no single definition of *Ubuntu*, all the above cited imply that *Ubuntu* is more than just a manifestation of individual acts” (Munyaka and Motlhabi 2009: 65). This means that it goes beyond physical individual persons and beyond the physical realm. Munyaka and Motlhabi are accurate to assert that *Ubuntu* is a spiritual foundation, an inner state, an orientation, and a disposition towards good which motivates, challenges and makes one perceive, feel and act in a humane way towards others. It is a way of life that seeks to promote and manifest itself and is best realised or made evident in harmonious relationships within society.

2.5.2. The Concept of *Ukama*

Ukama is a Shona word which means relationship and an understanding of reality in terms of interdependence (Murove 2009: 316). Grammatically, *Ukama* is an adjective constructed *U-Kama*. The *U-* is an adjectival prefix and *Kama* is an adjectival stem. *Kama* becomes a verb meaning to milk a cow or goat. In Shona thought the idea of milking suggests closeness and affection (Murove 2009: 316). Those related by blood or marriage are *hama* which is a noun (Dale 1994: 127). In a nutshell, *Ukama* means being related or belonging to the same family (Murove 2009: 316). However, in Shona, as in many other African languages, the meaning of *Ukama* is not restricted to marital and blood ties. Most cultures in Africa tend to see all people as *hama* (relatives) (Murove 2009: 316). Michael Bourdillon captures the inclusiveness of the term when he asserts that, “unrelated persons can adopt the terms *sekuru* (grandfather) and *Muzukuru* (cousin) towards one another to express a friendly relationship, reflecting the typical relationship between mother’s brother and sister’s son” (1976: 34). For instance, instead of an elder being addressed as a ‘madam’ or ‘sir’, such a person within the categories of *Ukama*, might be addressed as *mama* (mother) or *baba* (father) in Shona, Zulu, or Ndebele, or *ntate* in Sotho or Pedi (Murove 2009: 316). Being human entails living in relationships, seeing one another as relatives, or seeking to establish this relationship as an actuality’ (Murove 2009: 316). In addition, Murove postulates that ‘among Africans, *Ukama* provides the ethical anchorage for human social, spiritual and ecological togetherness (2009: 317).

The concept of *Ukama* is not necessarily to be conceived as a mere social construct. There are some Shona proverbs that point out the idea of *Ukama* as an existential reality permeating

everything that exists. In *Tsumo-Shumo*, Shona Proverbial Wisdom and Lore, Mordikai Hamutyinei and Albert Plangger presented the following proverbs on *Ukama*: “*Ukama Hausukwi nemvura hukabva* meaning relationships cannot be washed away by water: *Ukama urimbo kudambura haubvi* meaning relationships are like bird lime; even after breaking they do not vanish: *Ukama igasva hunozadziswa nokudya* meaning relationship is a half-measure, it finds its fulfilment in sharing”. (1974: 218-20). In all the proverbs, one looking through will see that what is common in all is *Ukama*. It stands as the only enduring entity. According to Murove, “the ethic of *Ukama* as constituting the wisdom and experiences of the community, is passed from generation to generation through these proverbs” (1999:14). For instance instead of instructing someone that sharing food with others is a virtue, a proverb is used to convey the message, “*Ukama igasva hunozadziswa nokudya* (relationship is a half-measure, it finds fulfilment in sharing). This proverb admonishes the selfish in its appeal to the *Ukama* ethic requiring one to share one’s wealth with others” (Murove 1999: 14). Thus, through “*Ukama* the community’s moral values are conveyed to individuals from childhood into adulthood and in social settings, individuals are frequently sensitized as well as reminded about the reality of interdependence from birth unto death” (Murove 2009: 317).

2.5.3. Language (Using San as the Case)

Language is another important cultural value in Africa. The inability to comprehend or speak one’s language is seen as a defect, or sometimes an insult to one’s culture. A particular culture can be defined by their language. For instance San languages, characterised by implosive consonants or 'clicks', belonged to a totally different language family from those of the Bantu speakers. Broadly speaking, they are two different and identifiable languages, namely the Khoikhoi and San. Many dialects have evolved from these, including /Xam, Nǀ, !Xu, Khwe and Khomani. Nǀ, previously called Hottentot, is the most populous and widespread of the Khoikhoi and San languages (Bleek, 1956).

Very little is known about the different dialects of South Africa's San people, as most of these, ancient languages were never recorded. Fortunately, the /Xam dialect, which is spoken by the San, was recorded almost in its entirety, thanks to the work of a German linguist, Dr WHI Bleek (1956).

/Xam speakers originally occupied a large part of Western South Africa, but by 1850, only a few hundred /Xam speakers lived in remote parts of the Northern Cape. Today, the language no longer exists, but survives in 12 000 pages of hand-written testimony taken down word-

for-word from some of the last /Xam speakers in the 1860s and 1870s. These pages record not just the /Xam language, but also their myths, beliefs and rituals. A comprehensive /Xam dictionary was produced by Dr Bleek at the time, but was only published years later (Bleek: 1956). This has served as a form of identification for the San people and their culture. Thus language can be a barrier to effective informed consent process.

For instance, South Africa as an African country has 11 major languages including English language which the consent form is most times written in. According to the latest Census in 2011, South Africa had the population of 51.58 million in 2011 and only 4 892 623 could speak English. Comprehension is one of the essential elements of a true informed consent. International ethical guidelines stipulate that informed consent must be given in a comprehensible manner to a competent person who freely decides to participate after understanding the information (NBAC 2001; CIOMS 2002; Marshall 2006). However, the amount and quality of study information required to engender comprehension of a potential participant is unclear. There are also divergent opinions among researchers on the level of comprehension a potential participant should reach to be able to freely decide (Ijsselmuiden & Faden 1992; Hyder & Wali 2006). In most African settings, the majority of research participants have low literacy, but informed consent documents are designed and delivered in a complex, lengthy manner that makes comprehension very challenging for the participants (Priestley et al. 1992; Jefford & Moore 2008; Falagas et al. 2009).

2.6. The San People and the New Code of Ethics

According to the South African History Online (2016), the San are deemed the first people in South Africa, the earliest hunter-gatherers in South Africa. This indigenous African people were also known as the “Bushmen” a term used by the European colonists that is now considered derogatory. The San populated South Africa long before the arrival of the Bantu speaking nations, and thousands of years before the arrival of the Europeans. The San people of South Africa have been studied by many scientists and researchers because of their rich heritage of rock art attributed to their ancestors. According to Lee (2002), the San represent an unspoiled natural humanity living in harmony with nature.

In March 2017, the San people in South Africa issued the first code of research ethics designed by indigenous African people. According to Daley, the major motivation behind writing a research code of ethics was from a study that was done and published in 2010. This study documented the genome of four San men in Namibia. The researchers did everything

legally, by obtaining appropriate ethical approvals from the Namibian government and their respective universities. Again, they obtained verbal consent from the participants through the help of a translator but the San leaders were not happy because they were not consulted about the research and they questioned the verbal process of obtaining consent from the participants (2017). This gave the San leaders the perception that researchers are only interested in fulfilling the legal process of obtaining consent and by doing this, they reduced the research participant to objects of research not subjects (Rachels 1986). Thus genuine and proper consent in an African context goes deeper than satisfying legal formalities (Lindegger, Milford, Slack, Quayle, Xaba, and Vardas, 2006).

According to the San Booklet (2017), there are four principles that need to be respected and recognized so as to facilitate ethical research among the San community. These principles are respect, honesty, justice and fairness, and care.

2.6.1. Respect

In this section of the research ethics booklet, the San people assert that they require “respect not only for individuals but also for the community” (San Booklet 2017:2). In their culture as Africans if an individual is to be respected it must start with the community. In essence they demand respect for their culture which includes their beliefs, norms of behaviour, and values (San Booklet 2017). They advise researchers to engage with them for the purpose of doing research with some level of sensitivity. This is because there are certain sensitive issues known by them alone but if they are respected and given the privilege to engage fully in the research with no assumptions, these issues will be revealed.

In short, the San people points out clearly that for them respect includes respect for their culture as well as respect for their relationship with the environment. Secondly, that respect for individuals used in the research requires the protection of the San’s privacy at all times. This means that when the privacy of the San community is protected, the individual privacy will be protected inevitably. Finally, the San assert that respect demands that their contribution to research is acknowledged at all times (San Booklet 2017).

This principle was established due to the fact that the San community has been disrespected in several ways. An instance is the Gonomics research in which their leaders were avoided; this was disrespectful to the San community. Photographs of individuals in their homes, of

breastfeeding mothers and of children underage were taken without obtaining proper consent from the community. As a result, their traditional values and social norms were disrespected.

2.6.2. Honesty

According to the San, they require honesty from all those who come to them with research proposals. They require an open and clear exchange between the researchers and their leaders. They demand that the language must be clear, not academic. Complex issues must be carefully and correctly described, not simply assuming the San cannot understand. There must be a totally honest sharing of information. Open exchange should not patronise them, and by open exchanges they imply that an assessment must be made of possible harms, or problems, for the San resulting from the research and these possible harms must be honestly communicated. Prior informed consent can only be based on honesty in the communications, which needs to be carefully documented. Honesty also means absolute transparency in all aspects of the engagement, including the funding situation, the purpose of the research, and any changes that might occur during the process. Honesty requires an open and continuous mode of communication between the San community and researchers (San Booklet 2017).

According to the San communities, they have encountered lack of honesty in many instances in the past. Researchers have deviated from the stated purpose of research, failed to honour a promise to show the San the research prior to publication, and published a biased paper based upon leading questions given to young San trainees. This lack of honesty caused much damage among the public, and harmed the trust between the collaborating organisation and the San. Another common lack of honesty is exaggerated claims of the researcher's lack of resources, and thus the researchers' inability to provide any benefits at all (San Booklet 2017).

2.6.3. Justice and Fairness

For the San, justice and fairness of a research require that the San are meaningfully involved in the proposed studies, which includes learning about the benefits that the participants and the community might expect. These might be largely non-monetary but include co-research opportunities, sharing of skills and research capacity, and roles for translators and research assistants, to give some examples among the San. This will create opportunity for the people as they are researched on. They also demand that any possible benefits should be discussed with the San, in order to ensure that these benefits do actually return to the community. As part of justice and fairness the San assert that they will try to enforce compliance with any

breach of the Code, including through the use of dispute resolution mechanisms. In extreme cases the listing and publication of unethical researchers in a “black book” might be considered. An institution whose researchers fail to comply with the Code can be refused collaboration in future research. Hence, there will be “consequences” for researchers who fail to comply with the Code (San Booklet 2017).

They have encountered lack of justice and fairness in many instances in the past. These include theft of San traditional knowledge by researchers . At the same time, many companies in South Africa and globally are benefitting from their traditional knowledge in sales of indigenous plant varieties without benefit sharing agreements, proving the need for further compliance measures to ensure fairness(San Booklet 2017).

2.6.4. Care

This section is rooted in relationship. It is a measure at which the researcher and the San community will employ through the research relationship. They demand that research should be aligned to local needs and improve the lives of San. This means that the research process must be carried out with care for all involved, especially the San community. The caring part of research must extend to the families of those involved, as well as to the social and physical environment. Excellence in research is also required, in order for it to be positive and caring for the San. Research that is not up to a high standard might result in bad interactions, which will be lacking in care for the community. Caring research needs to accept the San people as they are, and take note of the cultural and social requirements of this Code of Ethics (San Booklet 2017).

This principle like other above mentioned principles was established because the San have encountered lack of care in many instances in the past. “For instance, we were spoken down to, or confused with complicated scientific language, or treated as ignorant” (San Booklet 2017: 3). In addition, failing to ensure that something is left behind that improves the lives of the San also represents lack of care (San Booklet 2017).

The above principles as postulated by the San are deeply rooted in the conceptual understanding of a person through the eye of the community. It is a culture that advocates for a communal understanding of an individual. This means that the community comes first before the individual. This is clear in their numerous reference to the San and the community instead of an individual. As mentioned above, the application of something that is

ontologically individualistic in nature will inevitably create a conflicting situation and for the fact that informed consent has been applied already in the alien soil of Africa, it will demand deconstructing the construct to deal with the conflict. This is why it is necessary to consider the theoretical framework of decolonisation in the area of medical practice as it will advocate for a principle that is culturally sensitive. The next part of this study will explore more on the idea of decolonisation that the researcher will employ in the study.

CHOOSING A CONCEPTUAL FRAMEWORK.

2.7. Top down/Deductive Approach or Bottom up/Inductive?

The moral judgement and decision making can be seen in two ways. These are according to Beauchamp and Childress (2013), the 'top down' approach and the 'bottom up' approach. The top down approach is based on the justifiability of a particular action through the application of various moral theories and principles. The bottom up approach is a form of justification that begins with concrete and unmistakable instances of good and bad behaviour and proceeds to the formulation of general principles that capture and distil our fundamental moral responses to the cases. Thus the traditional moral theory is a conceptual system that attempts to define and guide the best decisions and actions. It investigates the question of what is the best way for people to live and what actions are right or wrong in particular circumstances. So, the traditional model of ethical reasoning seeks to resolve issues of human morality by putting in place concepts that will define ideologies like good and evil, right and wrong, virtue and vice, justice and crime. And there are set out principles and theories to be followed while making a traditional moral judgment.

The following are some examples of traditional moral theories:

- Consequentialism argued that an act is right if and only if it produces the best consequences. Thus right and wrong depend solely on consequences, as opposed to on intrinsic moral features such as fidelity and truthfulness.
- Utilitarianism postulates that an act is right as it tends to promote pleasure and or happiness and wrong as it tends to promote the opposite of happiness. Thus one should always act so as to promote the greatest happiness of the greatest number.
- Deontology ethics by Immanuel Kant: here he argued that nothing is good or right except a good will, and a good will is one that wills to act in accordance with the moral law. Thus an act that is done out of respect for moral law rather than out of

natural inclination is a good act. He saw the natural law as a categorical imperative. This means that its content could only be established by human reason alone.

These and many other traditional moral theories provide different perspectives about how moral judgments are made / or societally condoned/justified. But in cases of ethical dilemma it is not sufficient. This is because each traditional moral theory looks at only one way of deciding what is right or wrong whereas in application of ethical theories to a case-base issue reason and happiness might conflict and then produce a dilemma. To deal with such dilemmas ethicists have come up with some alternative models of ethical reasoning.

The traditional top down models of reasoning are monistic and reductionist, i.e. based on a belief that all moral considerations can eventually be grounded in one ultimate principle in terms of normative foundations that can provide solutions to all moral controversies. In this regard, Beauchamp and Childress argue that the traditional ethical theories are reductionist. By this I mean that they reduce the essence of morality to one all-embracing principle, and a single all-encompassing standard of morality of right action. Not considering the fact that the moral reality is too complex in itself. The complexity of our decision making is aggravated even more by non-moral conditions and there is no guideline on how to choose the right approach or how to determine the right moral and non-moral reasons that tend to justify our actions. The inability to give a guideline on justifying our actions establishes that the traditional moral theory is unable to resolve the question about the relationship between universal and particular. That is, it cannot state clearly how to apply the general universal principle to a specific case. This is the reason why the top down approach does not succeed (Beauchamp & Childress, 2013).

Beauchamp and Childress argue otherwise: traditional moral theories have internal problems and are not very helpful in the resolution of moral dilemmas and practical issues.

Considering Beauchamp and Childress' critique of traditional top-down approach, I will choose the bottom-up approach because the traditional moral theories as demonstrated above appeal to an abstract universal notion of personhood and could be means of intellectual and cultural imperialism. This is because biomedical ethics deals with real people in particular situations, i.e. particular persons in particular contexts or contextualized persons.

In addition biomedical ethics is also rooted in culture. If there is no cultural practice and way of life, there will be no biomedical ethics; the four assumed globally accepted biomedical ethical principles are autonomy, beneficence, non-maleficence and justice formally established by Beauchamp and Childress in 2013 to address biomedical issues in the West and this is why they are rooted in the Western-European traditions. However, the Western-European world is different from African. Constructively, biomedical ethics in the real sense cannot function without a culture because its elements and principles are based on culture and traditions (Chukwunke, Umeora, Maduabuchi and Egbunike 2014). Thus the case study approach seems to be most suitable, instead of imposing some sort a priori values and principles, it allows for the ability to distil them from the particular cases that are historically, culturally and otherwise situated and this research assume that Africa-situated cases should distil African values and principles.

Again, this research is opting out of monistic approach and opting for a pluralistic one because of its compatibility with the idea of multiculturalism. As Wildes and Kevin (2007) argue, that Culture has a deep relationship with morality. Thus, the concept of multiculturalism links directly to the reason why morality should be pluralistic and diversify. He asserts that morality encompasses the moral practice which is embedded in culture which we see as a way of life. Ethics seeks to examine those practices and moral systems that are embedded in cultural practices. Hence advocating for a multicultural society, which a lot of people do nowadays, will be synonymous to advocating for a morally pluralistic society.

2.8. Moral Pluralism

2.8.1. Brody's version of moral pluralism

It is of the idea that there is an irreducible plurality of the fundamental moral principles in accounting for conflicts (Ross, 1930). For Brody, there are three angles that pluralistic theory can be defined from. These are the ontological, logical and epistemological and they are all about using several independent moral or non-moral properties to draw conclusion to the action in question (Brody, 2003).

According to Brody, the moral world is messy because it has many different aspects which cannot be reduced or eliminated (Brody, 2003). Brody also asserts that when one examines a monistic theory, especially when it is addressing difficult cases or 'exceptions', like moral dilemmas there are appeals to other moral properties. There is a temptation to build in other moral properties in monistic theories. Based on this examination, Brody argued that it is a

fundamental mistake for moral philosophy to assume that any one aspect can capture the whole of the moral reality. With this statement he demonstrates the understanding that the moral world is complex and cannot be reduced to a particular aspect if one is to have completeness in addressing moral issues (Brody, 2003).

Apart from Brody's defence of pluralism, he suggests a clear model of analysis of the relationship between cultural pluralism and moral pluralism. Though Brody's pluralistic theory is complex it can be very influential and useful in the aspect of cultural inclusiveness. This is because Brody is not trying to argue and simplify moral pluralism and moral differences into 'sameness', rather he is arguing for a model of pluralism rooted in the wide variety of moral appeals.

2.8.2. Ross' Model of moral pluralism

The central notion of the alternative approach is *Prima Facie duties* – which literally means from the first sight which is different from absolute duties that hold in all circumstances or conditional duties (Beauchamp & Childress, 2013).

Ross argued that “*Prima Facie* suggests in this approach that one is speaking only of appearance which a moral situation presents at first sight, and which may turn out to be illusory, whereas what he is speaking of is an objective fact involved in the nature of the situation or more strictly in an element of its nature, though not as duty proper does, arising from its whole nature” (1930:20). For example, is it your duty to keep a promise when you may be in a position to avert a serious accident by failing to keep it? There are two *Prima Facie* duties here; the first is to keep a promise and the second is to relieve distress. The circumstances in the particular case can make the latter a greater duty, looking at the seven principles of *Prima Facie* duties which are the guidelines in decision making. These are fidelity, reparation, gratitude, justice, self-improvement, non-maleficence, and beneficence.

- Fidelity is a duty to fulfil (explicit or implicit) promises/agreements which one has entered. This is a duty to keep ones promises and contracts and not to engage in deception.
- Reparation is a duty to make up for the injuries one has done to others.
- Gratitude is the duty to repay others for past favours done for oneself. Thus it is a duty to be grateful for benefactions done to oneself and if possible to show it by benefactions in return.

- Self-improvement is a duty to improve one's own condition in these respects. It is to act so as to promote one's own good in the aspect of health, security, wisdom, moral goodness and happiness.
- Non-maleficence: these are provider-centred (like doctors) factors that advocate that no harm should be done nor allowed to happen to an individual. It also promotes protection of the interest and happiness of the other persons and of society at large.
- Beneficence: these are treatment-focused factors that concern itself with the welfare of an individual, foster his or her interest and happiness.
- Justice: these are community-centred factors that request that everyone should act fairly, distribute benefits and burdens in equitable fashion and resolve dispute by means of fair procedure taking into account that this research will focus on Africa. (Ross 1930).

The reason I prefer Ross' model in regards to this research is because the *Prima Facie* duties stem from relationships and from the analogy above, it is clear that the African notion of person is relational. Although, Ross' model is Western, it gives credit to relationship, obligation and responsibility. Thus Ross' model seems to be a most suitable model to follow. From the above argument, it is clear that there is an obvious difference between the Western practice of biomedical ethics and African practice of biomedical ethics. In that case, the Western informed consent processes do not apply in African context but does not mean that it cannot be adopted to suit the situation in Africa and it does not also mean we do not need it all. Let us consider the following case in Kano state, Nigeria (Ten 2011:148-165).

In 1996 a meningitis epidemic erupted in a village in Kano state; a predominantly Muslim North of Nigeria. Thousands of children were in danger of dying or becoming disabled. A state hospital offered free medical assistance to affected children in cooperation with Doctors without Borders. A few weeks after the eruption of the epidemic, a research team arrived from Pfizer, which is the largest pharmaceutical company in the world. As a 'humanitarian gesture', the company offered a new antibiotic for the treatment of the children. Pfizer treated about 200 children. However, it was not explained to the parents or the children that the drug (Trovan) was an experimental drug and that the treatment of the children formed part of an existing scientific research study. Some children received the experimental drug and others received the approved medication. After 2 weeks the research team concluded their study and they returned to the United States, although the epidemic was still in full swing. In 1996

Pfizer applied to the American FDA (Food and Drug Administration) to commercialise the drug. In 1998 the drug was approved only for use in adults in the United States, while it was not approved for use in Europe at all. In the meantime information surfaced that the treatment could have serious side effects.

Later research highlights the following unethical actions in Kano:

- The drug had never been tested on children before the project in Kano.
- Early research on animals had indicated the possibility of liver damage.
- During the research study half of the children received only half of the normal dosage of the approved medication; the aim was to make the experimental drug look good.
- Parents and relatives were never informed of the fact that experimental drugs were used and that they could receive free treatment with safe and effective medication from Doctors Without Borders.
- Neither the consent of parents nor the assent of the children was ever sought.
- Eleven children died over the course of the research study.
- A local medical doctor who was supposed to lead the research was only the leader in name.
- The letter of consent from the ethics committee of the local hospital was forged because no such committee existed.

Since this occurrence, clinical research has been exported to Eastern Europe, Africa, India and China with even more frequency. From 2002 onwards the number of new applications for research in America decreased by 5.5% due to the strict regulation of drug trials, while it increased by 15% in the above mentioned regions. From 2007 onwards more research has been done outside America than in the country. Forty per cent of clinical experiments are performed in developing countries (Ten 2011).

There are several reasons why research is being done in the developing world like Africa, but one reason is the conflicting situation of informed consent and autonomy. The export of clinical research to countries that do not have a strong ethical infrastructure has caused and will still cause many problems, as the above-mentioned example shows (Ten Have 2011:605). In court cases after the experiment in Kano, Pfizer claimed that the ethical

principle of informed consent had not been necessary because there was no international norm that required it. The company asserts that the norm was a typically Western norm and could not be enforced in non-Western countries. It is agreeable from the above argument that argued Western notion is alien to African context but! It does not follow that there should be no informed consent at all; just that it has to be re-interpreted within the framework of African values.

It is for this reason that I have decided to explore the possibility of implementing the principle of informed consent in the context of African biomedical ethics without undermining the traditional values and belief systems. This is because biomedical ethics will grow and engender medical practice in Africa, if and only if, it dismantles the encrustation of foreign values and views the African thought material in its true light rooted on the traditional African values and indigenous heritage. Thus, bioethics in Africa has to considering the codes and concepts as identified by Dein and Bhui (2005). They postulate that when it comes to doctor/patient relationships argue that the notion of autonomy varies considerably between cultural groups. What should be considered more in the doctor-patient relationship should be elements like loyalty, integrity, solidarity and compassion (2005).

Looking at Dax's case, In July 1973, Cowart, a then pilot in the Air Force reserve, and his father were visiting a tract of land that his father was thinking of purchasing. The land lay in a small valley and, unbeknownst to the Cowarts, a gas leak had caused the valley to become filled with propane gas. After surveying the land, the Cowarts returned to their car, and the sparking of the ignition set the gas on the floor of the valley ablaze, severely burning both men. According to Cowart: 'I was burned so severely and in so much pain that I did not want to live even in the early moments following the explosion. A man who heard my shouts for help came running down the road, I asked him for a gun. He said, 'Why?' I said, 'Can't you see I am a dead man? I am going to die anyway. I need to put myself out of this misery.' In a very kind and compassionate caring way, he said, 'I can't do that.'

Cowart's father died en route to the hospital, but Cowart himself survived the ride to the hospital, despite the fact that he was refusing medical treatment because he felt he would not be able to regain his former level of activity. Cowart's injuries included the loss of both his hands, eyes, and ears, and the loss of skin over 65-68% of his body.

While in the hospital, Cowart continued to insist then that he wanted to die; his doctors refused. Cowart says that he was "forcibly treated for 10 months" although he continually

begged his doctors to end treatment and allow him to die. Instead, Cowart was subjected to medical treatments, which he likened to being "skinned alive" on a regular basis, including being dipped in a chlorinated bath to fight infection and having the bandages covering his body regularly stripped and replaced. He was provided with only a limited supply of painkillers, since their risks were not well understood at the time. He was denied access to means of communication by which he might seek legal assistance in ending the treatments. He attempted to commit suicide on several occasions, but was prevented each time.

Cowart eventually healed enough from his injuries to be released from the hospital. Although blind and without functioning hands, he was able to earn a law degree from Texas Tech University in 1986, and now has his own practice. Cowart legally changed his name to "Dax" because he was often embarrassed to respond to "Donald" only to find that a different person was being addressed.

From the above case, his individual autonomy was denied and can be perceived as morally wrong in the Western concept and perspective but from an African perspective, it is morally right because when analysing a case from an African perspective the most important thing to be considered is family/community. Although, in the case of Dax, the only immediate family member he had left gave her consent for the treatment. In a traditional African set up, consent from the extended families which will be at the hospital immediately after the accident will be required too.

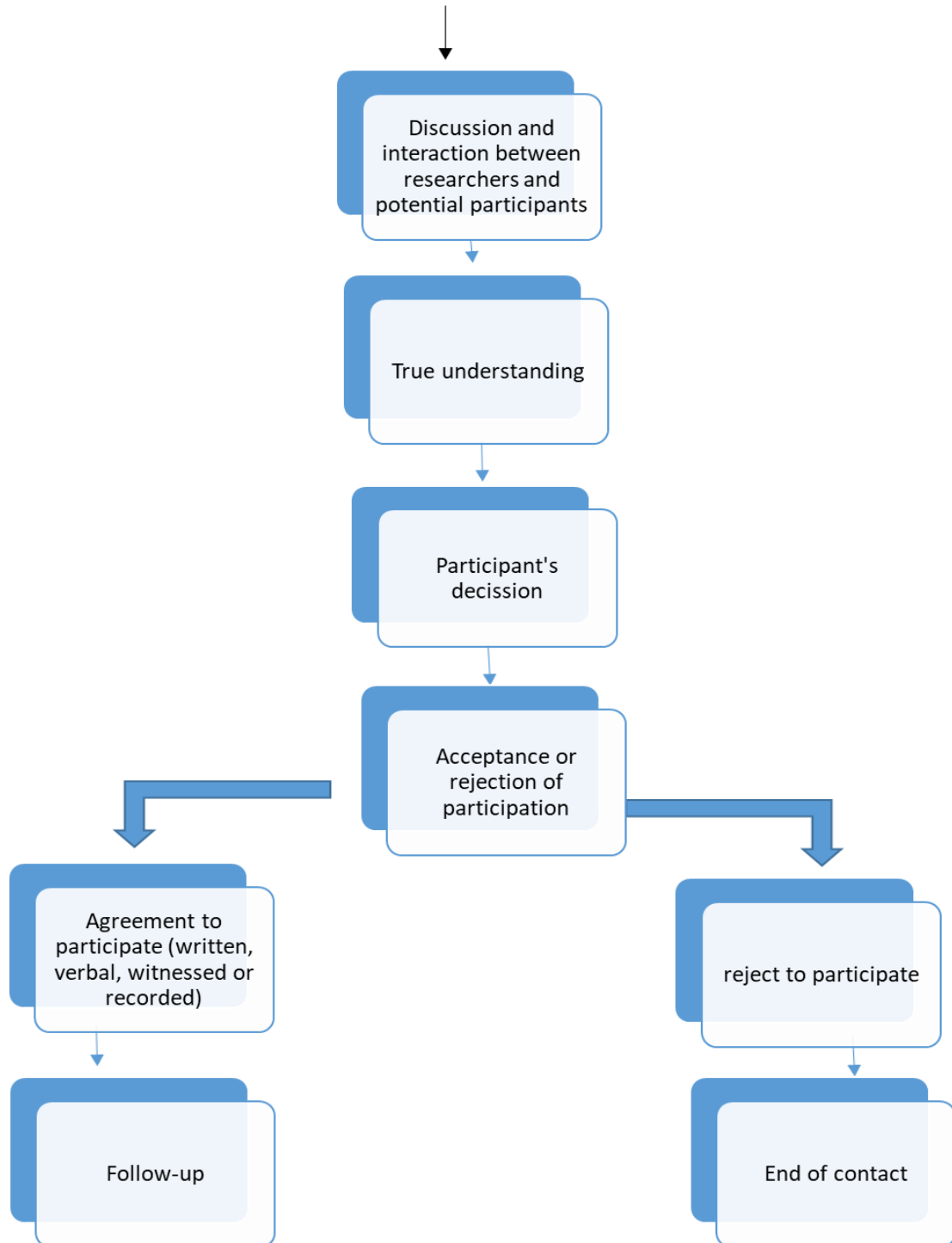
So, in the case of a research or trial the whole community consent will be required. For instance, In the Kassena-Nankana district of Northern Ghana, local cultural values and practices, such as the role of traditional chiefs, influence many aspects of daily life, including participation in research. Researchers are expected to ask these leaders for permission to invite community members to participate in their studies. Traditional chiefs are highly respected in the community. They derive their position by being born into a "royal" family and inherit their leadership role. At the highest level is a paramount chief, whose kingdom typically encompasses a population of 10,000-20,000. Divisional chiefs, sub-chiefs and elders report to the paramount chiefs. A community is composed of compounds, each of which contains one or more households in which several generations of a family typically reside. Each compound has a "head," usually the most senior male. Researchers must consult the head before approaching members of the compound to participate in a study (Ngom,

Debpuur, & Akweongo, 2003). As a contrast in Dax's case consent from the family head would have been required too.

The process of consulting leaders and household heads about any new activity in the community, including research, follows a long-established protocol. For example, the protocol for approaching chiefs involves paying respects to the chief and the presentation of small gifts of kola nuts and a bottle of spirit. The research is explained to the chiefs, and then permission from chiefs to conduct activities in a community is given verbally. Similarly, household heads give verbal consent to approach individuals. Only after these steps have been completed may researchers approach individuals to invite them to participate in research (Tindana, Kass & Akweongo, 2006). In an African concept of informed consent, obligation, values, family, parent and community leaders needs to be considered. When these are taken into consideration then we can conclude that there is a proper relationship between doctor/patient and researcher/research participant. In addition, (Fitzpatrick, et al., 2016), state that when conducting research with indigenous populations, consent should be sought from both individual participants and local community. There is an informed consent process model that was proposed by Bhutta (2004) and it is closely related to this idea and attached below is the model.

Fig 2.1: A proposed conceptual frame work for the process of obtaining informed consent by Bhutta (2004)

Information provision and sharing by the research team with the participants and community leaders (communal assent and agreement with/the family/community)



For the above model which was proposed by Bhutta (2004) the first step, the research team provides full and transparent information about the research and the participants right in a manner that can be understood by the potential participants. The whole research project especially the nature of sponsorship, the benefits of participation, and the responsibility for care and complications, must be carefully explained to participants. They must be given the opportunity to question the research team in order to clear up ambiguities and obtain additional information on the research.

The second step is of critical importance for Bhutta: this is the part that the participant must understand what is being asked of him or her. This can occur if the information about the research is presented in a manner that is simple yet conveys the key elements of the proposed research. Although this a difficult step in the process, it is also very crucial that this interaction occurs when the potential participant is in a calm frame of mind. There might be difficulty in understanding the research depending on the participant's awareness of the content and how much time is spent explaining it, their opportunities available to interact with the research team and their literacy levels. However, illiteracy must never be taken to mean that a potential participant is unable to comprehend complex information, but it does mean that the information may need to be presented differently.

The final step is for the potential participant to freely agree to take part in the research or reject to take part in the research. Therefore not only must the participant understand the project but he or she must also be competent to give his or her consent.

2.9. Conclusion

The above model is ideal and applicable to some cultures as it still privileges individual autonomy over communal and relational autonomy. So far, the researcher's attempts to compare and contrast Western and African notions of personhood and, stemming from them traditional values and imperatives, shows that there are salient differences between the two frameworks. These differences have important implications for ethics of biomedical researcher-human subjects of research and medical practitioner-patient relationships, especially in terms of informed consent and its application. However, this research seeks to develop and propose an informed consent model that can be applicable in Africa taking into account that the communitarian system in Africa advocates for relational, communal and family decision making instead of an individual.

CHAPTER THREE

CHOOSING A METHODOLOGICAL FRAMEWORK

3.1.Introduction

The effectiveness of all research is based on some underlying philosophical assumptions about what constitutes valid research and which research method(s) are appropriate for the development of knowledge in a given study. In order to conduct and evaluate any research, it is then important to know what these assumptions are. This chapter outlines the philosophical assumptions and details the design strategies underpinning this research study. This study considers Khan's argument that the research methodology defines the accuracy and credibility of the information collected and the overall reliability and credibility of the research (Khan, 2012). The analysis of the philosophy, strategy, design, administration, and the research ethics in the following sub-topics show justifications and the possible influence of each method or technique applied in the course of the research. However, before the above mentioned subtopics are presented, it will be necessary for the researcher to first present the identified paradigm for the research.

3.2.Research Paradigm

According to Terre Blanche and Durrhein (1999), the research process is underpinned by major assumptions regarding ontology², epistemology³, and methodology⁴. According to them a research paradigm is an all-encompassing system of interrelated practice and thinking that define the nature of enquiry along these three dimensions.

The term paradigm originated from the Greek word *paradeigma* which means *pattern* and was first used by Thomas Kuhn (1962)⁵ to refer to a conceptual framework shared by a

² The term Ontology refers to a branch of philosophy concerned with articulating the nature and structure of the world (Wand and Weber, 1993, p. 220). It specifies the form and nature of reality and what can be known about it.

³ Epistemology refers to the nature of the relationship between the researcher (the knower) and it denotes (Hirschheim, Klein, and Lyytinen, 1995) "the nature of human knowledge and understanding that can possibly be acquired through different types of inquiry and alternative methods of investigation." (p. 20).

⁴ Methodology refers to how the researcher goes about practically finding out whatever he or she believes can be known.

⁵For a detailed discussion, understanding and history of the development thoughts and problems addressed see: Kuhn, T (1962): *The structure of scientific revolutions*. Chicago: University of Chicago Press. 172 p; Kuhn, T.

community of scientists which provided them with a convenient model for examining problems and finding solutions. Kuhn (1977: 173) defines a paradigm as “an integrated cluster of substantive concepts, variables and problems attached with corresponding methodological approaches and tools...”. According to him the term paradigm refers to a research culture with a set of beliefs, values and assumptions that a community of researchers have in common regarding the nature and conduct of research (Kuhn 1977). A “paradigm implies a pattern, structure and framework or system of scientific and academic ideas, values and assumptions” (Olsen, Lodwick, and Dunlop, 1992:16).

The ontological and epistemological aspects of paradigm concerns what is commonly referred to as a person’s worldview which has significant influence on the perceived relative importance of the aspects of reality of that person. According to Lather (1986: 259) research paradigms inherently reflect our beliefs about the world we live in and want to live in. Based on this belief, Guba and Lincoln (1994) distinguish between positivist, post-positivist and postmodernist enquiry, grouping postmodernism and post-structuralism within ‘critical theory’. The nature of reality assumed by positivism is realism, whereby a reality is assumed to exist; in contrast, post-positivism assumes that this ‘reality’ is only ‘imperfectly and probabilistically apprehendable’ (Guba and Lincoln, 1994: 109). Post-positivism is viewed as a variant of the former positivism, but they are both objectivist.

Critical theory adopts a more transactional and subjectivist epistemology where “the investigator and the investigated object are assumed to be interactively linked, with the values of the investigator . . . inevitably influencing the inquiry” (Guba and Lincoln, 1994: 110). Whereas the aim of positivist and post-positivist enquiry is explanation, prediction and control, the aim of critical theory is critique and emancipation (Willmott, 1997). Thus, as the aim of the research is to explore and analyse the application of informed consent process in Africa and if necessary suggest a new process that will be culturally sensitive the best theory to apply is critical theory as well as critical postmodernism (Gephart 1999).

3.3.Critical Theory/Critical Postmodernism

(1970): The structure of scientific revolutions (2nd Enlarged Edition). Chicago: University of Chicago Press 210 p and also Kuhn, T. (1996): The structure of scientific revolutions (3rd Edition). Chicago: University of Chicago Press. 212 p.

The critical postmodernism is a combination of two somewhat different worldviews—critical theory and postmodern scholarship (Gephart, 1999). Critical Theory is a tradition developed by the Frankfurt School in Germany, based on the German tradition of philosophical and political thought of Marx, Kant, Hegel and Max Weber. Postmodernism is a form of scholarship which emerged in part through the work of French intellectuals such as Lyotard, Derrida and Foucault (Gephart, 1999).

Though they are derived from different views, they are broad rubrics for intellectual movements rather than specific theories, yet “they are essential parts of social semiotic analysis. Critical Postmodernism is less radical in its approach and is a growing field of study that is moving beyond the supposedly radical postmodernism. This paradigm is a force of liberation that engages an on-going conflict with the powers of oppression and seeks to bring about educational reform” (Reeves and Hedberg, 2003: 33).

Critical researchers assume that social reality is historically constituted and that it is produced and reproduced by people (Myers, 2009). Although people can consciously act to change their social and economic circumstances, critical researchers recognize that their ability to do so is constrained by various forms of social, cultural and political domination.

Therefore, “critical scholarship seeks to transcend taken for granted beliefs, values and social structures by making these structures and the problems they produce visible, by encouraging self-conscious criticism, and by developing emancipatory consciousness in scholars and social members in general” (Kincheloe and McLaren, 1994: 138-157). The aim is to openly critique the *status quo*, focus on the conflicts and constraints in contemporary society, and seek to bring about cultural, political and social change that would eliminate the causes of alienation and domination.

The paradigm of critical theory encourages evaluators and instructional designers to question and also to evaluate the cultural, political, and gender assumptions underlying the effectiveness of the instructional product or programme (Reeves and Hedberg, 2003). The critical theory seeks to deconstruct the "hidden curriculum" or "text" and search for the "truth" and "understanding within the social context” (Reeves and Hedberg, 2003:33).

According to Gephart (1999), the goal of critical postmodernism is social transformation to displace the existing structures of power and domination by opening opportunities for social participation among persons previously excluded and dominated. The task in critical

postmodern analysis has been to deconstruct discourse to reveal hidden structures of domination, particularly dichotomies (e.g., Western/African) and then reconstruct or offer alternative, less exploitive social arrangements (Boje, 2001). This is linked directly to the application of decolonisation theory in the study.

A critical postmodern manifesto resists the reduction of all postmodern theories into the camp of naïve interpretivism or relativistic social construction (Boje, 2001). Critical postmodern research has often focused on discourse at the micro level, in contrast to a somewhat more macro level focus in critical theory research. It often uses conventional positivist and interpretivist methods; thus, rather than methodological differences it is a commitment to dialectical analysis and to critical/postmodern theory which most clearly differentiates critical postmodern research from all other research paradigm (Gephart, 1999).

3.4. Research Methodology

According to Myers (2009), the research method covers the underlying assumptions, research philosophy, design, data collection, and data analysis. There are many distinctions in the research modes and methods but the most common classifications are qualitative and quantitative.

Qualitative research is naturalistic; it attempts to study the everyday life of different groups of people and communities in their natural setting. "...qualitative research involves an interpretive, naturalistic approach to its subject matter; it attempts to make sense of, or to interpret, phenomena in terms of the meaning people bring to them (Denzin and Lincoln, 2003). According to Domegan and Fleming (2007), "Qualitative research aims to explore and to discover issues about the problem on hand, because very little is known about the problem. There is usually uncertainty about dimensions and characteristics of problem. It uses 'soft' data and gets 'rich' data" (24). According to Myers (2009), qualitative research is designed to help researchers understand people, and the social and cultural contexts within which they live. Such studies allow the complexities and differences of worlds-under-study to be explored and represented (Philip 1998:267).

As many scholars (like Domegan and Fleming 2007: Henning, Van Rensburg, and Smit 2004: Denzin and Lincoln 2003: Richardson 1995), have argued that human learning, experience and culture is best researched through the use of qualitative methods, this is the approach adopted in this study. This is because in qualitative research, the researcher wants

to understand and explain, with arguments and with the use of data, what the studies' phenomenon or phenomena are about (Henning, 2004). Qualitative research takes its inquiries further from the question of what happens, to questions of how and why things happen as they do.

In selecting a research methodology, Guba (1981:76) suggests that "it is proper to select that paradigm whose assumptions are best met by the phenomenon being investigated". This study seeks to critically explore the possible conflicts surrounding the application of the principle of autonomy to the general population of Africa and thereafter, draw inference on the possibility of applying a principle that is more cultural sensitive. This will be done through personal interaction with people who have had the experience of implementing the process of informed consent as well as the principle of autonomy in Africa and it will be a good approach to use qualitative research method because this will allow the researcher to understand the participant role in the event and their perception of the new code of ethics by indigenous African people (the San). This point and the above definition of qualitative research justify the use of qualitative method for this study, as the study involves understanding not only what the nature informed consent is, but also the implication of its application in the general population of South Africa. Besides, qualitative research approach involves allowing for an open-ended views on the themes studied, in order to allow for better understanding and explanation of the phenomenon under discussion. The research philosophy of this qualitative study will rely on literature and empirical data.

3.5. Research Philosophy

The development of an articulate, credible and reliable research depends significantly on the effective application of a suitable research philosophy for the particular study. The choice of research philosophy according to Jost, et al. (2012), depends on the type of the research, the objectives, and the possible strategies applicable. This research aims to explore the possible conflicts that will arise in the application of informed consent process to the general population of Africa, taking into account that informed consent is rooted in the Western-European traditions. To meet this aim, the study seeks to explore the understanding of the nature of informed consent among biomedical researchers. It would also assess the possible conflicts that will arise in the application of the principle of medical ethics to the general population in Africa. This will be to determined reasons and grounds for conflicts and controversies that its application can engender in the context of African traditional values and

belief systems. Also, the research will argue for the use of an alternative approach to explore the concept of informed consent in doctor patient/research and research participant relationship in Africa. The above, will reveal peoples understanding, perceptions as well as dilemmas around informed consent process in the context of African traditional values and belief systems. The application of methods that uncover these concerns and integrate expert opinion on the issue is critical for the development of a comprehensive and articulate research (Check & Schutt, 2011). This study employs the case study as well as the phenomenological qualitative research technique to capture the experiences, and concerns around the application of informed consent process in Africa and the perspectives of researchers about the new San code of ethics.

The application of the qualitative research technique to the research enhances the effectiveness of the data collection and analysis for the development of a credible and well-researched study. According to Hays and Singh (2012), the qualitative research method allows the analysis of a smaller sample without the isolation of variables. The method offers critical insights in the development of studies that focus on capturing perceptions, thoughts, concerns and experiences. The application of this method in this research offers a broad base for the analysis of the issues in the research questions. In addition, Rubin and Babbie (2011) argue that the explorative nature of the qualitative research study approach allows an in-depth understanding of issues that influences people. The use of this method in traditional and health care research allows the researcher to capture the experiences and explore them extensively to understand phenomenon and issues under study. The application of this method in the study is greatly important for the development of an articulate, credible and reliable study.

3.6. Research Strategy

The choice of the research strategy is critical for the development of good research. The sequential development of research from the identification of the topic, the investigation of the possible, the influence of such research on the field and the society, and its contribution to the choice of the research philosophy and other key research areas facilitates effectiveness and the comprehensiveness of the study. The research strategy influences the development of a credible and reliable research. According to Rubin and Babbie (2011), the research strategy plays a fundamental role in shaping the research, the accuracy of the data collected, and the reliability of the data analysis techniques. The research strategy determines how accurate the

data collected is, in relation to the topic of discussion or under study. Effective data collection strategy allows the integration of precise, accurate, and appropriate data in research. Further, according to Belk (2006), the development of a good research strategy defines the ability of the research to meet the objectives of the study and influences the applicability of the research in future.

According to Hays and Singh, (2012), the identification of the most effective research methods before the commencement of the study is crucial for developing a good research. This research identified the qualitative research method. Moreover, the identification of the data collection techniques is equally essential for the enhancement of effectiveness in the development of the study. While the research principles, universal research ethics, and guidelines for research are important for research, the research strategy defines and ensures that the researcher(s) follows all the necessary guidelines/principles and ethical practices in the collection and analysis of data. In studying possible conflict between the South African traditional values and belief systems and informed consent process in biomedical ethics and getting researchers perception of the new San Code of ethics, this research applies in-depth interview data collection and thematic content analysis.

According to Speziale and Carpenter (2011), a good research strategy comprises of different research components such as an excellent research design and research paradigms that enable effectiveness in data sampling, collection, and analysis. In investigating and exploring the possible conflicts that may arise in the application of the principle of biomedical ethics (autonomy) to the general population of African, taking into account that core African concepts like *Ubuntu* advocates for communitarian living and the principle of autonomy advocate for individuality and individual decision making. There is bound to be a conflict in the application of autonomy to a group of people that celebrate community, family and relationship. This study seeks to use a qualitative method as mentioned above to explore this conflicts and as a qualitative research, it employs the critical postmodernism paradigms to enhance the effectiveness of the research (Jost, et al, 2012). Thus, the data collection and analysis in this research was influenced by critical postmodernism research ontologies.

The interviews will allow the identification of the perspectives and experiences and the integration of the paradigm will outline an in-depth understanding of the factors. Furthermore, Check and Schutt (2011), relate that the interpretivist approach is flexible enough to allow the integration of the inductive research philosophy, which integrates

qualitative techniques and facilitates better research. Coyle and Lyons (2013) state that the inductive approach generalizes specific reasoning to understand the perspectives and experiences of the participants. This makes it an effective paradigm for application in qualitative research.

3.7.Data Collection

The researcher interviewed 12 medical researchers at UKZN and the data from the interviews was analyzed in combination with data available through publications. These data included The San code of ethics (2017), the HIV/AIDS Vaccines Ethics Group (HAVEG) Report 2006, and the Principle of Medical Ethics by Beauchamp and Childress (2013). The research design that was used is therefore an analysis of the principles of medical ethics and the possible conflict that may arise in the application of individual autonomy in Africa. The data as mentioned above are as a result of empirical interviews and published books, articles in academic journals, newspaper articles and thesis materials. With the data from these sources, the study was able to draw reasonable conclusion and make suggestions based on the research problem and questions.

3.8.Research Administration

The researcher applied an in-depth interview method in the collection of data and information concerning the application of the principle of biomedical ethics to the general population of South African and the possibilities of reconciling the possible conflicts that may have arisen in the application. The process requires the identification of research participants and for the purpose of the research, medical researchers and practitioners were identified as the target population and the target number was 12. The research applied a random sampling technique in choosing the participant at the initial stage of the research. According to Bazeley (2013), the application of the simple random sampling technique proves effective in the development of a group that represents the population effectively. Below is a tabular presentation of the participants

Table 3.1: Sample presentation of the Research Participants

		Age	Race	Gender	Field
1.	Participant 1	64	White	Female	Clinical Research Laboratory
2.	Participant 2	38	Indian	Female	Clinical Trial

3.	Participant 3	72	Indian	Female	Paediatric Nephrology
4.	Participant 4	53	African	Female	Chair BREC
5.	Participant 5	46	African	Female	Medical Technologist in Clinical Pathology
6.	Participant 6	39	African	Male	Gynaecologist
7.	Participant 7	57	White	Male	Medical Researcher
8.	Participant 8	56	African	Male	Medical Ethics, informed consent and Traditional medicine
9.	Participant 9	37	African	Male	General Practitioner
10.	Participant 10	65	White	Male	Bioethics Committee
11.	Participant 11	34	Coloured	Male	Medical Law
12.	Participant 12	74	White	Male	Medical Law

However, the researcher discovered that this technique was not very effective as the research involved speaking to researchers, lecturers and practitioners in medical field who already have busy schedule. Thus, the researcher decided to switch and adopt the snowball sampling method. Snowball sampling may simply be defined as: A technique for finding research subjects. One subject gives the researcher the name of another subject, who in turn provides the name of a third, and so on (Vogt, 1999). Snowball sampling can be placed within a wider set of link-tracing methodologies (Spren, 1992) which seek to take advantage of the social networks of identified respondents to provide a researcher with an ever-expanding set of potential contacts (Thomson, 1997). This process is based on the assumption that a ‘bond’ or ‘link’ exists between the initial sample and others in the same target population, allowing a series of referrals to be made within a circle of acquaintance (Berg, 1988).

The participants in this research were medical researchers in university of KwaZulu-Natal who have had the experience of implementing informed consent process in Africa. Moreover, the sample involved four professors, six academic doctors and two medical doctors. They were between the age range of 37 to 72. In-depth interview was administered to the participants and the interview guide below was used.

Interview Guide

1. What are the important aspects of an ethical research project for medical researchers

2. What are the strategies you adopt as a principle investigator to meet this criteria?
3. Are there any limitations in the application of these criteria to the general population of Africa?
4. What is your opinion on informed consent in Africa?
5. How successful is the application of the principle of autonomy in the general population of Africa?
6. Are you aware that the San people designed a new code of ethics? (if no I will explain)
7. What do you think about the San code of ethics?
8. What are the possible contributions of the San's code of ethics to medical research and practice in Africa?
9. Looking at Ross' theory of *Prima Facie* duties, do you think that adopting a principle that is more cultural sensitive will engender the relationship between researcher and research participants?
10. Is it possible to reconcile the concept of informed consent with the traditional African values and norms of behaviour taking the San code of ethics as a case?
11. What is the suitable method for the recognition of arising moral conflicts and controversies and their resolution with respect to traditional values and beliefs?

These are the questions that were directed to the participants but as the interview progresses there were few changes in the interview guide. For instance, question 3 and 4 referring to the general population of Africa was changed to general population of South Africa. This is because most of the participants were not very comfortable with talking about the whole of Africa as it was too broad and vague for their understanding and experience.

Secondly, it was also discovered during the research that going to each and every participant to explain about the San Code of Ethics was time consuming especially for participants who have other engagements. In addition, this research will be explaining from my perspective and that is subjective to what I think is important. Thus, the researcher decided to email the booklet to participants before scheduling to meet for discussion. This process rendered,

question six irrelevant in most cases. These changes contributed to the effectiveness of the data collection.

The interview was conducted in different offices in University of KwaZulu-Natal especially, medical school, public health and law departments where the potential participants were first informed of the purpose of the research and allowed to participate without coercion. According to Belk (2006), interviews are effective for outlining different aspects of the topic under study. In this research, open-ended interview were administered. Speziale and Carpenter (2011) posit that open-ended questions allow the respondents to include personal experiences, perceptions, and attitudes concerning the topic.

The semi-structured and unstructured interviews and the open-ended questions used in the interview allowed the participants to offer information about their perceptions, attitudes, and feelings. The analysis of the information and data requires the application of an effective approach. According to Coyle and Lyons (2013), the application of the content analysis technique allows the effective analysis of the information. Çuhadar (2014) argued that the approach is effective in analysing the captured perspectives, feelings, attitudes, and thoughts. The research adopted a thematic content analysis of the available data in order to make some evaluations and thereafter, draw inferences. Thematic content analysis is apt for a descriptive presentation of qualitative data (Anderson 1997), an approach which this study used. Anderson also suggests that thematic content analysis is used when the study involves identifying, examining, and reporting patterns or themes within a data (1997). Presented below is the code representation of each participant in the study;

Table 3.2: Code names for participants

Codes	Interpretation
F	Female
M	Male
R	Respondent
Number	Age of the respondent

For instance RM74 will refer to the respondent who is a male and is age 74.

This study involves identifying the contrast between informed consent principle of autonomy and South African traditional values and belief systems. Specifically, it involves analysing the application of informed consent principle of autonomy in South Africa. This was helpful in understanding and determining the impact that medical research has in South Africa taking into account the fact that the rules and norms of informed consent in bio-medical ethics are predominantly informed by Western-European medical and moral traditions with major emphasis being placed on the principles of respect for autonomy.

3.9. Research Evaluation: Validity, Reliability and Rigour

Some researchers doubt the credibility of qualitative research on the ground that the facts therein can be easily manipulated for polemical motives. Hopkins (1980) asserts that when using secondary data, researchers can easily attached meanings and interpretations to the phenomena as they desire (cited in Miriago, 2014). In general, positivists often question the trustworthiness of qualitative research, perhaps because their concepts of validity and reliability cannot be addressed in the same way in naturalistic work (Shenton, 2004:63). Researchers like Silverman (2001) and Pitts (1994) have tried in their research to demonstrate how qualitative research can incorporate measures that will respond directly to the issues of validity and reliability in their qualitative studies. This research adopted the following criteria by Guba (1981) to show it validity and rigour.

1. **Credibility:** According to Lincoln and Guba, (1985), ensuring credibility is one of the most important factors in establishing trustworthiness in a research. Thus to promote and show that everything in this research are accurately recorded, the following provisions were made:
 - I. The researcher obtained adequate and proper permission from the gatekeepers of the institute (in the case of this research the institute is University of KwaZulu-Natal). The researcher also established a communication process with the participants with the aim of sensitizing them about the research and what they will be expected to contribute to the research.
 - II. There were strategies to help ensure honesty in the informants. The study created an environment that will give the participants the ability to decide to take part and offer data freely.

- III. There was frequent briefing of the progress of the research with my supervisor and there was be an opportunity for academics and researchers in the field of population and health to review and scrutinize the work.
 - IV. There was also a high degree of reflective commentary in the research. Thus, my comment and comments from other academics and members of the school was points out in the research.
 - V. There will also be an examination of the research by an internal and external members checking the data collected, and interpretations/theories framed in the research. Thus, there will be a thick description of the phenomenon under scrutiny. This was done through conference presentation.
2. Transferability: The research will provide background data to establish context of study and detailed description of phenomenon in question to allow comparisons to be made.
 3. Dependability: the research will further adopt “overlapping methods” in-depth methodological description to allow study to be repeated where necessary.
 4. Confirmability: To show confirmability, the research will employ the following
 - Triangulation to reduce effect of investigator bias
 - Admission of researcher’s beliefs and assumptions
 - Recognition of shortcomings in study’s methods and their potential effects
 - In-depth methodological description to allow integrity of research results to be scrutinised
 - Use of diagrams to demonstrate “audit trail”.

3.10. Research Limitations

The principle of bio-medical ethics, looking at informed consent puts great emphasis on individual autonomy and it is predominantly informed by the Western-European medical and moral traditions which renders the African traditions and values unrepresented in the practice of medical ethics. This is because African traditions and values advocates more for communitarianism instead of individualism. For Africans emphasis are placed on concepts

like *Ubuntu* and *Ukama* and these concepts find their meaning in the deep understanding of relationship, sharing, interconnectedness, and interdependence of people in the community. So, what makes one human in African culture is close or intimate relationship with others in the community and this includes sharing everything including decision-making. With this, it is obvious that the principle of individual autonomy in informed consent collapse, in its application to the general population of Africa, as African communitarian ethics focus on the interest of family, community and society instead of an individual. There might be a conflict in the application of the Western principle of medical ethics in the general population in Africa.

3.11. Research Ethics

The concerns under study in this research are ethical. This is because the research is looking at the ethical dilemmas that will arise in the application of the principle of biomedical ethics in the general population of South Africa. The research is looking at South African traditional values and belief systems and informed consent process in biomedical ethics and research. It also reviews the perception of researchers concerning the San new code of ethics. The investigations in the research are highly ethical and, failing to consider ethics in the research would end up overstepping the ethical issues. In conducting the research, there is a need for the research to avoid approaches that might affect participant rights (Danis, 2012). Moreover, the participants must be informed beforehand of the purpose of the research and the different scenarios of applying the information they offer (Hoonard & Hamilton, 2016). This research considered these aspects of ethics and ensured that participants only participated willingly, without coercion, and were informed of the research objectives and the application of their information in the research.

CHAPTER FOUR

RESULTS AND PRESENTATION

This chapter presents the findings of the study and is structured in the following way:

Firstly, it will look at the most important factor that influences ethical research for medical researchers. Secondly, it will look at informed consent in South Africa. Furthermore, it will look at the limitation, dilemmas and conflicts that arose in the application of informed consent process in Africa. It will also present the perception of researchers at University of Kwa-Zulu Natal (UKZN) concerning the new San code of ethics and how it relates to the conflicts of informed consent in South Africa. Finally, the research will present the possible way of reconciling the concept of informed consent with the traditional African values and norms of behaviours. It will also seek to propose a suitable method of the recognition of the arising moral conflicts and controversies and their resolution in respect to traditional values and beliefs.

4.1.Ethical Medical Research

Participants were familiar with and defended the four principles of autonomy, beneficence, non-maleficence, and justice. RM56 summarised these as follows:

“One doing a medical research has to start by respecting the autonomy of the research participant, secondly, the researcher must make sure that the research is beneficial and make sure that the risk of the research is minimized, and finally the principle of justice is to be applied at all stages to make sure that resources are equally shared between people whom research are being done on and for those to which it is being benefited”.

He specifically highlighted that in a research, it is not always the case that the research benefits the participants directly but instead, the broader community. While all four principles were acknowledged, some participants went on to highlight a specific principle that they found particularly important in their experience.

For example, the tension between clinical practice and research was encapsulated in the ethical principle of beneficence. This is because when one approaches a medical practitioner he/ she is doing so because he or she is ill and needs to be cured, and not because they are eager to participate in a research study.

“the most important I’d say it is beneficence because medical practice primarily come in as an intervention and therefore coming as an intervention means it not a primary tool or excised in the normal day to day..... it only comes when it becomes necessary when somebody is sick and therefore amongst the pillars of the ethical codes that part of beneficence then must come in like on above the others in whatever you do you must ensure you are going to benefit the person who is coming to you for that particular attention or whatever they come to you for” (RM37)

In addition to the four principles, some participants note that as a researcher or physician one would need to take into consideration the critical aspects of confidentiality, empathy, care and competency on the side of the researcher or physician. RF72 emphasized on this when she asserts that

“as a researcher or physician, you have got to have.....confidentiality, you must be competent in what you are doing so as to be able to access the patient completely, you must be able to show that you care and to do this you got to have compassion and empathy and you must advocate for your patient or research participant. It is your responsibility as a physician or researcher to do this with integrity, care and a spirit of enquiry”.

However, these aspects are not the primary focus until proper informed consent has been obtained, and for this reason the principle of autonomy was prioritized. Participants note that it was not only individual researchers who prioritized this principle but that ethics committees reviewing study protocols for potential approval focused a lot of attention on this principle. As RF53 clearly points out that in every research

“you need the informed consent and that's why most people would stress on the fact that the principle autonomy must be respectedmost people argue that there is no principle more important than the informed consent which is based on the principle of autonomy. And it gives people the freedom to make choices to take part or not. As an ethics person, I would think, and I know it. And as a reviewer as well, I stress that on informed consent a lot. I think almost all ethics committee focused on that a lot as well. It would appear that informed consent is the most important one

because that's where we think that if we don't get it right and don't understand things may go wrong. So we need to make sure that the participants are not exploited”.

Most of the participants assert that obtaining proper consent, which is directly linked to respect for autonomy, is the most important criteria of an ethical research for medical researchers. According to RM56,

“Respect for autonomy is very important and this is actualized in clinical terms by obtaining informed consent from the individual who is being asked to participate in research as a primary obligation”.

In addition, RF72 posit that

“One of the most important aspect of medical research is that you got to have consent”.

Furthermore, participant RM74 states

“the job that I've done is that I have sat on the university Ethics Committee for I don't know twenty years or something at one stage and always what we had to make sure was that proper consent are made by individuals not by any cultures or groups somebody says you've got to participate or you can't participate it is done by individuals”.

This links directly to the next section of the research which is informed consent.

4.2. Informed Consent

Informed consent in itself is a process in which the research participant or patient consent to take part in a medical research or treatment. It is a process that is supposed to be undertaken without an undue influence. This process has its own stages and RM56 outlined this properly by asserting that

“There are key elements that you need to have for informed consent to be considered valid. One of the most important things is that informed consent is not just about signing a consent document, Informed consent involves full information disclosure, it must make sure that there is full comprehension of the information by the by the research participants or research subjects, the consent must be voluntary, that is, the

person must be free to agree or disagree to participate in the research and when we talk about voluntary, there has to be absent of coercion, has to be absent of undue influence and the participants must not participate out of fear or any other reason that will make them participate even when they are not freely making the decision to do so. There must be undue inducement. You must not induce them with money or any other thing that could influence the participant into accepting to participate. Finally, there must be justice, you know individuals if they have to spend their time and effort to get involved in a research they have to be compensated. If they happen to drop out of the research people who are vulnerable must be compensated for their time. That is part of justice in other words you cannot use their time without their agreement that will be exploitation. There are a lot of things you have to do to make sure that the research is done in a proper manner and you must inform them how long the research will be. Thus, you must inform them about the benefit, you must inform them about the risk. If there is no benefit or if the risk is minimal you must inform them. Also you must protect their privacy, maintain confidentiality of the participants. All these are the key elements that are necessary for the project and for the investigator. So to meet all these criteria, you have to make sure that you have a comprehensive informed consent documents, a detailed protocol that is approved by the appropriate ethics committee”.

South African common law also stipulates the necessary requirement for informed consent to be valid and RM74 highlights this when he notes that:

“There are a number of things according to the common law. Informed consent means you must have knowledge of what you are consenting to; you must appreciate the consequences of what you are consenting to, you must agree to that not being offered pervasive incentive or anything it must be free voluntary and you must consent, to all the consequences. OK that's what the Common law says”.

In addition, RF46 presented a criteria for informed consent set out by the National Health Act. She states

“The National Health act also gives you criteria for informed consent. They say that the participant needs to be given all of the different options, you've got to give first of all be told what to use what they're going to do with you they have to give you all the

different options, but we can do this, that or whatever it is. You got to then tell them the consequences of the research and so on as well. And they've got to get enough information given in a language they can understand at a level they can understand so if they're not very educated you've got to talk very simply so they understand and in the language which they want”.

The above is for the general consent process, but when it comes to extremes cases like drug trials, the process is different. In this aspect, RF46 went on to say that in such cases the participant will need to be taken care of for the rest of their life. She states

“When you're dealing with research of course you've got to have a situation where not only do they consent to the procedures and its consequences they need to know what's going to happen once the research finishes because if you put me on medication and the trial is over then you withdraw the medication what's going to happen to me? And so increasingly as you probably know ethical committees have answer to that and they say you must carry on with the treatment afterwards”.

Thus, as postulated by most of the participants, informed consent is the most important aspect when it comes to ethical research for medical researchers. However, the process of applying informed consent in Africa and the above mentioned criteria has intrinsic limitations and these limitations will be explored in the section below.

4.3. Informed consent in Africa

Informed consent is difficult to define in an African context. According to RF53 *“informed consent will be difficult to define it in an African context”*. This is because informed consent is rooted in the Western liberal tradition of individuality. As RM56 puts it,

“informed consent in Africa is a little bit complicated because informed consent in its original idea is derived from a Western conception of libertarian right in other words individual rights which doesn't really translate to African cultural norm because if you look at it from the point of view of Ubuntu ”.

To emphasize more on this, RM37 states that

“The issue of informed consent and whatever goes with it. it's ancient its taboo. It's transplanted it's ideas or ideologies that are transplanted into our communities we don't have we don't have that and I do not recall in at any point in our lives as black

people where we went out and toyitoyi⁶ to say that we want To be autonomous as such”.

The traditional African values and norms of behaviour do not advocate for autonomous existence. Africans have always existed as communities and this is one of the key common concept around African communities. RM56 in line with this same view state that

“the South African concept of Ubuntu because Ubuntu is not universal but it gives an idea of the African communitarianism and if you go to places like Ghana or other African countries you have to get the interest of the community and the interest of the community sometimes overrides the interest of the individual. So when you compare to the Western concept of informed consent whereby the rights of the individual always overrides the right of the community so there is a conflict there or there is a difference”.

The research discovered that sometimes informed consent in Sub-Saharan Africa can be useful although it is in an imperfect thus, it has limitations. These limitations range from the fundamental differences in understanding of the principle of autonomy to language, vulnerability, a lack of Western education, spirituality, and the constitution and these are discussed in more detail below.

4.1. Autonomy

The application of the principle of autonomy in Africa has been unsuccessful and this affects directly the application of the Western informed consent process, because the African values and belief systems advocates for communitarianism. Something that is intrinsically autonomous will not flourish in Africa. This is clear when RF53 shared her experience of researching in a rural community in Northern Kwa-Zulu Natal. She discovered that to implement autonomy and privacy in African communities is very difficult. She states

“For me to talk to the mother and the child, the granny and the father must give me permission. It means now, they are the ones who are allowing that person, so that person is not, there is no autonomy in her because she is not allowed to decide whether she wants it or not she must first get consent from these two other people or the mother in law, must say yes or no or even father in law. You see so that her

⁶This is to protest

autonomy is affected she cannot voluntarily say no am going to take part. She has got to wait for husband or gogo or mother in law you know”.

This makes it clear that African research participants are not necessarily going to think as an individual but rather as a member of a group, who is strongly vested in the existence of other members. This according to RM56, is the primary obstacle when it come to the application of the conceptual understanding of autonomy. He states

“The primary obstacle in translating the informed consent as it is in the Western construct to the African construct is that the people will not even understand the concept of autonomy because they don’t think as individuals”.

This mind set according to RM57 makes medical practice challenging. This is because when people come to the hospital, they often do not come alone but they are brought in by the whole family, including the extended family. However, even if they come alone at the time, he notes that whatever you do, you have to involve the whole family and this affects medical interventions sometimes. He states

“in African settings, people come as families. They are brought in by families and even if they do not come with families, whatever you do to them it affects their families and in terms of medical intervention, it creates a bit of a challenge because you can sit one on one with the person whom you believe to be autonomous and everything. Then you discuss all the issues that are on the table as far as their conditions are concerned but the very same person sometimes you can have a 57 year old sitting in front of you in your senses that you can never be more matured than this person, there are as mature as it can get. But the person will tell you that before this intervention I need to go home and speak to my mother”.

Similarly, RM37 shared his experience of working in a community hospital and the first patient had developed multi-drug resistant tuberculosis. He acknowledges that in the rural community, the culture of *Ubuntu* was still intact and the ideology that an individual is part of the community is still at play. In some cases he had to wait for the patient to go home and tell the people what is going to happen to him and he respected that because he knew after everything the patient will be sent back to his family where he is a brother, father, uncle and son. He states

“I worked in a remote area where the the culture is still intact you are not an individual you are part of the community when I see you I see you as the representative of the community or of even the family. Like in this instance this man has spoken to me about the fact that he is married and he also has to speak to his mother before he can leave and that also meant to us that whatever we do to this person it means they might also be affected. So, whatever we do with him we also now have to go outside and go communicate with the family and we kept him for about two months”.

Some participants assert that the successful application of the principle of autonomy will be impossible except one is dealing with the issue of paternalism that has been at play in South Africa for years. RM37 states

“From my experience, I will say that except we are talking about the autonomy against paternalism that I will advocate for. However, in most cases the person is the person with their community, the autonomy that needs to be entranced is the one that fight paternalism. This is because the one that fight paternalism is the one where this person has to make a decision whether he is informed by the decision of his family or not. But I myself as a practitioner must not be on his neck as to what he needs, or he does not need because that’s where we come from as South Africans in terms of the history where people decided for us that’s why am saying some of these issues they don’t come from vacuum they come from our terrible past and how we implement them is another issue. So, if autonomy means taking away paternalism from the practitioner then by all means but if the practitioner insists on you being autonomous on your family but when he cuts off both of your legs he sends you back to your family then there is a problem”.

Here, dealing with the individual as an individual might cause a bigger conflict between your practice and the community. RF72 states

“Applying autonomy was very very difficult, at a point we even had to break the rules so we could get the work done and make sure that the community was cared for. We couldn’t worry about the individual we had to worry about the community”.

One thing that contributes greatly to the failure in the application of the principle of autonomy in Africa is the community/family structure. One of the participants sharing her

experience during her PhD research states that she had to go through a lot of process before she could speak with her research participants. She states

“Firstly as we enter each homestead there is the head of the homestead, you must ask permission from that head. My focus was the mother and the child but there is the father or the granny. I have to ask permission of the head to find is there a child who is less than two years. They say yes. I say can I see the mother they say what you need her for. I ask permission from the head of the homestead and then the head will allow me and then in the case where the mother is a teenager now I need permission from the mother of that young mother. So it is just and when I was interviewing because the family sees a stranger it’s a homestead there are about maybe five structures in one house. It’s a homestead. So, we all come here, it’s not just me and you, everybody comes here to listen to me and implementing privacy, there is difficult you try to tell them no no no I just need this one but they want to see what you going to do” (RF53).

This can be attributed to the idea that the communal mind set is deeply embodied in the African psyche thus to suddenly think as individuals will be difficult. The participant went on to say that the process would have been more tedious if her research assistant did not understand the local dialect of the people. Thus, her experience and the experience of other researchers made language one of the limitations that came up repeatedly in the research so it will be discussed in-depth below.

4.2.Language

This contributes greatly to the comprehensibility of the informed consent document. One of the things that came out in the research is the fact that the informed consent document should be in a language that is understandable for the research participant or patient. To reiterate few quotes that come up in the research;

“Informed consent involves full information disclosure, it must make sure that there is full comprehension of the information” (RM56).

In addition RM74 states

“During informed consent, the participant has got to get enough information given in a language they can understand and at a level they can understand”

This is in most of the ethical declarations and most ethics committees advocate for this. However, the limitation in this aspect is that as Africans we have multiplicity of languages but yet most of the informed consent documents are written in English. Participant RM56 emphasising on this states

“In South Africa we have 11 official languages so if you have a consent document that is for instance provided in IsiZulu to a Xhosa speaking, obviously there will be a conflict in understanding and the same applies to providing a consent document in English to a group of South Africans who are not educated”

There will be a requirement that the consent documents are translated to the language of the participant and the researcher has to be sure that the participant is able to read it.

4.3.Education

In addition to the language of the informed consent document, the lack of education among some potential research participants, is problematic to the process of informed consent. Education contributes greatly to one’s ability to comprehend the informed consent process and document. Some of the participants assert that they have experience that the more educated you are, the more you are able to understand the criteria/implementation of informed consent. Participant RM34 puts this clearly when he states;

“Among the rich Africans, there is a level of comprehensibility in terms of informed consent because they are more educated in the Western educational system and they have a reasonable form of income, they know the consumer right and they are able to ask questions because they have been educated”.

However, as lack of education and poverty is still widespread among Africans resident in rural areas, this creates a vulnerability in these communities as noted by RM56

“The African people that are consenting, majority of them are not educated and this is a vulnerability because it makes them vulnerable”.

This leaves most Africans in a position in which they have to consent to something that they do not fully understand. This also led them to agree because the person presenting the research looks educated and sounds like he has their best interest at heart. Hence, they go in with the mind-set that there is some form of benefit without weighing the risk and benefit

properly. This frantic move is attributed to poverty most times, thus, poverty as a limitation will be discussed below.

4.4.Poverty

This limitation has a connection to education in the research. Most Africans, as mentioned above, lack education because they do not have the necessary facilities and the financial structure to afford education. This has led to the contextual understanding that most African people live in poverty. One of the participants shared the result of a study he conducted in this area. He states;

“We conducted a study in South Africa and we found out that almost 65% of the general population of South Africans that were going to public hospitals have no jobs nor a form of income including grant” (RM56).

The above statistics means that in every 100 people who goes to a public hospital, 65 of them have no income. This is the reality of most African people; it is not just limited to South Africa and it contributes greatly to their vulnerability. Poverty, as well as lack of hope, exposes most African people to the risk of accepting to participate in a study that they do not really know the danger in it just because there are incentives. Participant RM56 states

“poverty makes them vulnerable especially in the context of research [where] any offer whether its medication, taxi fare, money are liable to induce them to agree because they are already in a very desperate situation”.

Anything the researcher offers them even if its treatment which is not even good enough to get them to accept, they will accept because there is no alternative. This is called therapeutic misconception even during clinical trials, there are situations by which people will agree to participate in the trial simply because they are going to get some medicine even though it might be useful to them or not because it is a 50% chance. The same happens with money that is paid or compensated for transportation or for time. People enrol in research just to get that money because they have not any other options so already consent is induced. In situations like this it is not informed consent, it is induced consent. Participant RM56 went further to prove this by stating;

“There are a lot of evidence of young people enrolling in research in Africa just because there is money which induces them to participate and it has to do with the fact that most Africans are generally poor”.

This is where values and codes needs to be implemented and a supportive system built to make sure that Africans are not exploited as objects instead of research subject. Thus, the implementation of African values and beliefs systems that will advocate for a relational consent process becomes necessary but before the research gets to that, the researcher will like to present other two limitations that came up during the research and these are spirituality and South African constitution.

4.5.Spirituality

The fact that Africans are ontologically religious came up in the research. Participant RF72 points out that for one to do a research successfully in Africa, one needs to take into account the fact that African have a deep sense of spirituality. She states;

“You got to know what the traditional values and belief systems are. The idea of community and one must recognise that Africans are a lot into spirituality. Thus you need to know what each religion mean to each of them”.

Furthermore, RF53 sharing her research experience, states that one of the limitations she had during her research was as a result of the spiritual beliefs of the people. She states that she was not allowed to weigh the children who were her participants as they believed that if a stranger comes and weigh their child, it might incur spiritual implications that will lead to the death of the child. She states;

“The belief the cultural system was that uhm because it a child they all always feel maybe you bringing bad spirit to affect the child. You bring bad spirit so they were not comfortable for us to weigh the child or to check the child they think when we go or the child maybe will die or will have complications”.

The last limitation or something that has contribute to creating a conflicting situation when it comes to research in Africa in relation to informed consent is the South African constitution and that will be discussed below.

4.6.South African Constitution

Most of the participants made references to how the South African constitution contributes to the compulsory implementation of the principles that advocates for individual autonomy and privacy in terms of decision making. RM74 puts this clear when he said that

“The constitution is quite clear nobody is supposed to have medical experiment done on them without their consent so it is clear that what is necessary is the individual decision”

In addition, RF53 asserts that in biomedical ethics committee, they follow the constitution because that is the basis for legal research process. She states;

“The biomedical ethics committee follows the constitution. That is why when we aim for a research we focus on a person, an individual not the people surrounding the person because that is the legal thing to do”.

This creates a dichotomy between what is legal and what is ethical. It also raises the question of how much the constitution is representing the people. RM37 puts these to rest when he confidently states;

“Uhm, you’d understand you really would appreciate that having done law and having done medicine and living amongst the communities for me I see the big gap between what the legislators are doing and what real life of an African person is”.

This statement illustrates the perception that there is a disjuncture between legislation that was developed to protect individuals as individuals, and the understanding of an individual’s place in what they believe to be an interconnected world. However, some of the participants interestingly did not see any conflict between the constitution and the belief systems of the African people of South African. Participant RM56 states;

“The constitution advocates for individual autonomy and respect for individual privacy and respecting one’s tradition is respecting their privacy and right, their cultural rights. Like South Africa has 11 languages and 11 of these languages needs to be respected and thus the consent form has to be provided in that particular person’s language. Even in the part of the constitution talking about informed consent section 6 of the National Health Act which is derived from the constitution it states

that informed consent must pay attention to the language and literacy level of the individual. So, I don't see any conflict there".

In addition, RM39 states;

"Yes, the constitution says individuals have right to privacy and bodily integrity but that right also talks about reproductive rights in the same section. Respecting individual right to privacy is respecting the right to involve or not involve their family, their spouse. In this context, it is a general application. If the individual says I want my family to take part in this decision about my privacy and the decision-making process. That is my right as a private individual to involve someone else in the decision-making process. So, it is not at conflict it not at conflict with the constitution at all. It is my private life to decide who I will or who I will not allow to take part in the decision-making process about my life. Thus, the right to privacy means you have the right to involve or not involve any body in your decision".

The conflict between the South African constitution and the practice of the people becomes a matter of individual perspective and understanding. Thus, any code can flow from there without directly disobeying the legislation. On this line of thought, many participants identified with the necessity for the San code of ethics which will be presented below.

4.4.San Code of Ethics

The participants perceived that the code of research ethics presented by the San is not fundamentally different from the other ethical codes. It was thought that even though they have put it in a very simplified language it still advocates for the same thing.

Participant RM37 states

"I think it is an integrated form of what the eh the four pillars of of medical ethics entail, but it is empty on community level because the issues of respect, the issues of recognising the chain of command are not there in medical ethics".

This is because the medical ethics, code and pillars are informed by the Western-European tradition. Hence, if one comes with the current medical principles to implement in African communities, the person will directly be ignoring the cultural structure and way of life of the people and it will be disrespectful. So, with the San code they are advocating that researchers give them what is their due which is respect, honesty, care, justice and fairness in return for

their collaboration with the work of the researcher. Some of the participants actually equate these to the demands required by most ethical codes. Participant RM56 states;

“The few things that I have identified is that 1). Is respect and that is what the San are saying that they want to be respected. Respect for autonomy is universal in other words people must be treated with respect. The San say, we don’t want to be exploited, in other words if there is any benefit, we want it to be shared and we want to be told you cannot just come and exploit us. They say we want researchers to care about what we are doing because they don’t care about us. In other words all these are included if you look at the new declaration of Helsinki in 2013; if you look at section 19, you find out that it is actually there ... Rights of vulnerable population groups that they must be involved in the decision making process and this part is newly added to the declaration”.

This gave a direct link to the state of Africa as presented in the limitations above. Based on the criteria of vulnerability as defined by Joint United Nations Programme on HIV/AIDS, (UNAIDS) Africans, because of their relatively poorer education, their lack of resources to obtain quality healthcare, poverty and issues of therapeutic misconception would be classified as vulnerable people generally. Consequentially, Africa is considered as a place where majority of people are vulnerable because many of them lack basic means of survival as well as the above mentioned limitation and the San will fall into this category. This puts them in a position where all ethical codes are supposed to take cognizant of their existence. According to Bioethics Commission in USA, ethical standards when dealing with vulnerable people have to be at its highest level possible. So, a researcher cannot deal with vulnerable African communities the same way they are dealing with people who are not vulnerable who are educated and who have choices.

According to participant RM56

“As a researcher, one has to pay special attention to the rights and dignity of vulnerable population groups”.

So, in that line of thought, the ethical code designed by the San is appropriate for their community. Moreover, if the code is implemented by researchers, it will not only be just a code of ethics for the San but it will be a tool that will engender ethical medical research and

practice and it will encourage other African communities to come together and form and a research code that is applicable only in Africa. In this light, participant RF53 states;

“Maybe they are now saying to us as Africans we need to define the informed consent in an African way because the way we are defining it is in a European or Western way you know maybe they want us to come up with a new definition because we are communal. We are communal beings”.

However, it will be necessary to note that the implementation of this code might develop a dilemma, and it is actually the dilemma that this research has been exploring. The current practice of medical ethics is rooted in the Western-European tradition as postulated earlier in the research. This is because when research is done in Africa or when ethics committees in Africa are reviewing a research protocol, they aim for an individual. So, if a research proposal/protocol is focusing on an individual and the researcher is planning to go and research among people who do not think individually there is bound to be conflict. Participant RF53 touched on this when she asserts

“When we do research in biomedical research we aim for A person or a participant we don't aim for those are the people surrounding that person. So we would say in bio medical research the person's privacy is violated because now you talking you want to talk to the mother you want to watch the mother breastfeeding during the research you don't want these guys to be there or before you do that you must involve other people”.

If the people surrounding the person as she mentioned are involved, looking at the biomedical principles, it can be argued that the privacy of the research participant and that of the researcher is compromised but in the context of African traditional values and belief systems it will be seen as a good thing, as it will prevent exploitation. As the San points out, if things are done properly and the leaders are respected and informed about every step of the research, the humiliating act of taking pictures of children and breastfeeding mothers and presenting them at international forum without proper consent will not be happening. One of the participant sharing her view on this states;

“When we see the horrible pictures of African people. You see them at conferences where they have taken the African children and African mothers suffering and you wonder did someone give permission for them to show those pictures”. (RF53)

So, there is a conflict; because in one way, the San code will prevent exploitation but on the other hand, if looked at with the general ethical code and norms as postulated by the Western world, it can be argued that the participants individual right and privacy has been compromised.

Further, some of the participants state that another source of conflict with the San code might be in the aspect of community consent as oppose to the individual consent. This is because if an individual decide against the decision of the community, it might lead to “ostracisation” of the individual from the community if it is not managed properly. According to RM56

“What happens if the San community represented by the leaders say it is okay to conduct a research and a particular individual say no I do not want to take part? The community might say oh you don’t want us to benefit from the research which we have already agreed that it will be of benefit to the family”.

So, it might lead to exiling the person from the community with the thought that he or she does not have the benefit of the community at heart. Thus, there could be a conflict between the right of the individual and the rights of the community. In this case, it will be necessary to develop an approach that will take into account the community as well as the individual. The sub-section below will look at how informed consent in Africa should look like and the possible way of reconciling informed consent process in biomedical ethics without undermining the traditional values and belief systems of the African people.

4.5.Possible Alternative Approach to Ethical Research in Africa

The first step in the direction of reconciling is to identify the dilemma in the application of the Western principle of bioethics in Africa. The problem is that the traditional conception of informed consent is rooted in the Western-European tradition. Thus, to deal with this, it will be proper to take cognisance of the fact that when obtaining informed consent, it cannot be done in the traditional Western way of obtaining informed consent where the interest of the individual will overwrite the interest of the community. The researcher has to respect the tradition and culture of the people. RM56 touches on this when he asserts;

“However, in terms of dealing with African traditional society, the researcher must also take into context the environment and the culture and that is what the San are saying in their code even though it is not very extensive, it is very simplified. They are

saying understand our values, our belief systems and if you look at the ethical principle there is something like the researcher must respect the environment”.

This is what the San are advocating for. They are arguing for respect, honesty and truthfulness and an appreciation of the fact that in Africa, a person is not a person on his or her own. The individual is a person through the community and by default the person becomes part of a community and whatever happens to the person directly affects the community.

“You cannot continue to say privacy, when that privacy is killing the community”
(RM37).

This justifies the fact that the San are demanding that before a researcher comes to conduct research in their environment, he or she must obtain permission from them as a group. It is after the researcher have explained to them as a group comprehensively, that he or she can go to the individual. However, it must be noted that this is not a new process as the current approach to ethics includes the emphasis that researchers must act appropriately within the context, including the cultural belief systems. In fact, where it is necessary, the researcher may be compelled to obtain community consent (declaration of Helsinki section 25). This is not only limited to the San people or South Africa, People have looked at places like Ghana in West Africa where a community believe strongly on community consent.

Thus, this is the area where there could be conflict, but if it is taken into context that the participants in the research are a group of people who have a different belief system, informed consent can be applied within that context. It is possible to reconcile informed consent process with the traditional Africa belief systems what is necessary, is taking informed consent and making it more cultural sensitive. Informed consent must have cultural plasticity and researchers cannot just apply it rigidly, it must be flexible depending on the culture.

Accordingly, as some of the participants presented, informed consent in Africa is different from the way it is practised in the Western world. In Africa, it is supposed to be a lengthy process that takes into account all the traditional values and belief systems and it has to be cultural sensitive. As RM56 puts it

“So if you are asking for the difference between the Western concept of informed consent and an African concept of informed consent, the primary difference is that in

Africa the interest of the community overrides that of the individual and in the Western world the interest of the individual overrides that of the community”.

Africans act as a group and the interest of the group is more important. So already there is a conflict because informed consent in itself advocates for individual right. Therefore, in the context of Africa, it will be necessary to look at informed consent from a community perspective. In other words, it will be necessary to involve the community in the informed consent process while in the Western construct it remains an activity only undertaken with the potential research participant.

However, it came out in the research that most ethics committees in Africa should also state considering the cultural norms of the people. This is because if a researcher submits a research protocol that advocates for individual autonomy, privacy and right whilst he is planning to go and research among people who do not think as individual, there is bound to be a clash as well as an unethical procedures judging from the angle of the traditional practice of the people. In the light of the argument, it was discovered in the research that even when ethics committees for instance like the one at UKZN try to be culturally sensitive they only look at the language as participant RF53 points out.

“So, usually the only thing that we stress in the cultural aspect dealing with informed consents is the language we take care of the language, we translate the informed consent into their language then we say we take care of the cultural”

Language is just one aspect that contributes to the values of an African person. There are many other common beliefs among Africans. These include: belief in ancestors, an understanding of an individual as communally constituted as well as a relational world-view. The concept of African informed consent has to take these things into consideration. This is directly linked to what the San people are saying. The San are saying that as a group, they want to be involved in decision about conducting research in their own environment as a group. This is because when this happens, their cultural beliefs and norms of behaviour will be respected inevitably. That is why they came up with their own code of ethics because the individual consent is not the most important thing the community consent is also important. However when this is compared to the current ethical declaration of Helsinki or the CIOMS or the World Health Organisation (WHO) guidelines they do agree that you can involve the community when you are obtaining informed consent among traditional groups like African

communities. However, within these codes or guidelines, the consent of that particular individual remains central and it cannot be overridden by community decisions. In other words if the San as a group say according to our code of ethics you can come and perform research you must still obtain individual consent from the person whom you want to use as participant and if the person disagrees then that consent is invalid.

However, it was also discovered that even though majority of Africans think communally, those exposed to education tend to understand the demands of informed consent as related to individual autonomy. In the light of this, RM56 states that *“there are a few people who are educated and will say am old enough to consent I don’t need my husband or family but in the same line there are certain individuals who will say look I cannot do this without consulting my family, my husband or my parents, the elders, sometimes they have to consult the ancestors and make sacrifices”*. The idea is that in Africa, these are some of the things a researcher needs to take into consideration, and this is the fact informed consent in the way that it is in the Western culture or Western practice cannot be translated directly into the African context, it probably will not work.

4.6. Perceptions of Ross’ Theory

The theory advocates for duties that stem from relationship. It is not about principles that one needs to respect in the process of research. Instead it is about the moral duties that one owes to the other in any relationship that is why they are called duties. If research is seen more as a relationship and not a professional responsibility, it will engender sensitivity of cultural approach. The researcher will be more sensitive in his or her approach with the knowledge that morally they owe to each other self-improvement, fidelity, repression, gratitude, justice, no harm, benefit. In relation to this participant RF72 states

“The theory is more applicable for the relational aspect. But one thing is that if you are setting up a relationship with the community, you need to give them time. You cannot come today and want to do it tomorrow. You have to give them time and then come back. That is what we found with the traditional leaders but they were very nice once they started. You know once there is time to iron out all the issues then it could work”.

Some participants state that the duties will only apply in the aspect of the researcher because it is not all research that directly benefits the individual participants for taking part in the study. RM56 states

“So, in the aspect of the researcher, the duties will apply because it will demand that the researcher treats his or her participants with those duties but in terms of mutual relationship, there is no mutual relationship because you are asking someone to do something that may not affect them at all but am not saying that this happens all the time. This is why there has to be consent because the benefit is mostly for the researcher and the community”.

One participant did not see the relevancy of Ross’ theory to my investigation, because he sees the theory as a tool that advocates for favouritism and nepotism. He states;

“Oh my answer about Ross’ idea is that I don’t agree with his views because I think they might promote nepotism and favouritism and it ultimately leads to corruption”.

This in a way gives credit to the argument, since the theory was used for this research on the same basis that it advocates for nepotism and favouritism. The argument in the research is focused on Africans traditional values and beliefs system and Africans advocates for communal structure because of their natural inclination to tribe, family and community. In a nutshell Africans tend to protect and represent people whom they believe they are connected to and this makes them prone to act in ways that can be considered as forms of nepotism or favouritism. Thus, Ross’ theory becomes appropriate for African studies.

4.7. Conclusion

The study has presented that the most important aspect of medical practice and research is the principle of respect for autonomy actualized through the informed consent process. Nonetheless, informed consent in its traditional form is rooted in the Western libertarian tradition. This is why it places more emphasis on individual right and autonomy. On the other hand, the San community developed a code of ethics that is community centred instead of the individual. This shows that most if not all African communities advocate for communal existence. Thus, the application of informed consent in its traditional form may create a conflicting situation in Africa. So, the necessity to develop an alternative approach to the ethical dilemma and conflict becomes eminent in the research. The following discussion chapter will present the research argument and explore more on the alternative approach using Ross’ pluralistic theory as the base.

CHAPTER FIVE

DISCUSSION AND CONCLUSION

The existing aim of the research is to contribute to the body of knowledge on the development of medical and health research and practice in Africa. It aimed to explore and analyze the dilemmas around the application of the principle of informed consent to the general population of South Africa using the San code of ethics as an example to initiate the discussion. The study presented the views and perception of researchers in the biomedical field at UKZN on the issues around informed consent in African and the possible ways of dealing with it. It also presented the perceptions of researchers on the San code of ethics and how it will engender ethical medical research and practice in Africa. The primary objective for the research was to analyze the ethical dilemmas of informed consent in doctor-patient and researcher – research participant relationship in the context of traditional African values.

It aimed to examine the dilemma that occur in this relationship through the practice of Western concepts of biomedical ethics in Africa, with the aim of ascertaining a possible way of implementing the principle of informed consent in the context of African bio-medical ethics without undermining the traditional value and belief systems using Ross' pluralist theory specifically, *Prima Facie* duties. The study sought to answer the question: What guiding principles would biomedical researchers be prepared to adopt in the African context to ensure that research could be conducted without undermining the traditional value and belief systems?

The chapter seeks to present the main qualitative findings in a summarized form and the relationship of the findings to the existing literature as well as the argument in the research.

5.1. Ethical Principles

This research explored the long-standing argument that started with Engelhard to Beauchamp and Childress (2001). Beauchamp and Childress (2001) argue that the four principles of autonomy, beneficence, non-maleficence and justice are of equal importance at every point of an ethical research study. On the contrary, Engelhard argued that the principle of beneficence and autonomy cannot be of equal importance. He argued that there is a point at which the benefit, particularly to the larger community, may be considered of sufficient significance that it may be determined that it outweighs the individual's right to the protection of the autonomous decision making process. The dangers inherent in this dilemma are so grave that

he posits that in every ethical research study, the most important principle should be the principle of autonomy (Beauchamp and Childress 2001). In the same way, the result from this research shows that many researchers in UKZN are of the same idea that the most important aspect of an ethical research for medical research is respect for autonomy and it is actualized through the informed consent process.

5.2. Informed Consent and its Limitation

This study found that for biomedical researchers, informed consent has become the central and defining feature of ethical contemporary medical research and practice. This is similar to the idea postulated by Manson and O'Neil (2007). They assert that informed consent is a central concept in the contemporary biomedical ethics and is seen widely as fundamental to medical and research ethics.

Furthermore, it was found that biomedical researchers perceived that the informed consent is a process that research participants and patients have to follow to make a research valid. The process or criteria states that Informed consent involves full information disclosure, it must make sure that there is full comprehension of the information by the research participants or research subjects, the consent must be voluntary, that is the person must be free to agree or disagree to participate in the research and by voluntary, it means there has to be absent of coercion, has to be absence of undue influence and the participants must not participate out of fear or any other reason that will make them participate even when they are not freely making the decision to do so, there must not be undue inducement. This means that a researcher must not induce his or her participants with money or any other thing that could influence the participant into consenting to participate.

There must be justice that is if individuals have to spend their time and effort to get involved in a research, they have to be compensated. If they happen to drop out of the research, vulnerable people must be compensated for their time too. In other words, you cannot use their time without their agreement that will be exploitation. As a researcher, you must disclose to the participants all the benefit that will come with participating in the research and risk must be minimized as much as possible. The privacy and right of the individual participant has to be protected. Similar process is postulated by the South African constitution and common law, the South African National Health Act, and other ethical declaration like the declaration of Helsinki.

Guidelines such as those promulgated by the Helsinki Declaration (World Medical Association, 2002), CIOMS (2002), the Nuffield Council on Bioethics (2002; 2005) and the National Bioethics Advisory Commission (2001) reinforce a commitment to transcending cross-cultural differences by mandating that the same standards be applied to research participants from both resource-poor and industrialized countries (Brody, 1998; Sugarman et al., 1998; Macklin, 2004). Research participants in any cultural setting, for example, should provide individual voluntary consent, and studies that could not be conducted in an industrialized country should not be implemented in a developing country. This idea advocates for the application of the same ethical codes and guidelines across all cultures in terms of informed consent. The purpose of this declaration was to reduce exploitation as much as possible especially in vulnerable communities. Nevertheless, it was discovered in this research that the problem of balancing universal and local standards for ethical conduct in biomedical research is challenging especially when investigators/researchers confronts the practical constraints of implementing a study in areas where traditional customs may be in conflict with international guidelines. This was perceived to be the case in research conducted in the African context by the participants.

Africa, considered as one of the impoverished continent that bear a disproportion burden of disease morbidity and mortality, due to lack of adequate health resources is also struggling to deal with the conflict between the general ethical principles and the traditional values and norms of behaviour. This is because the application of general ethical principles underlying guidelines for research is difficult to accomplish without knowledge of the cultural context within which a study will take place. This is as a result of the fact that informed consent which is the most important ethical principle when it comes to ethical research cannot be globalised because it is culture dependent. “Anthropologists have described culture as a symbolic system representing ideas, values, cosmology, morality, and aesthetics shared by individuals and groups” (Kuper 1999:227). This definition goes against the idea of developing a general ethical principle because culture is particular to a group thus it is necessary that the principle that guides informed consent process is flexible to fit every culture. The principles advocated for by the general ethical guidelines are not flexible, as they are dependent on the Western-European libertarian tradition. This is why it has great emphasis on individual autonomy and privacy but this is bound to fail in its application in Africa.

Although one cannot speak about African culture as if it is a homogenous phenomenon, however, this study while affirming the diversity among African culture and its ability to respond to contemporary social and political realities, it also collaborates with Peter Kasenene's position that "despite variety, there is a common "Africanness" about the culture and world-view of Africans" (2000:348). There are commonalities and beliefs that are shared by indigenous African societies such as a belief in ancestors, an understanding of an individual as communally constituted as well as a relational world-view (Murove 2014). It may be argued that these commonalities should be the foundational basis for a discourse in African bioethics as well as guidelines and ethical codes.

In this line of thought, Akin Makinde argued that "theories and practices of medicine have a cultural basis and it is because of this notion of social embeddedness, that African medical practices are inextricable from African culture and belief systems: From this point of view the concept of illness, diagnosis, treatment, life and death must also have a cultural dimension" (Makinde 1998: 91). Makinde's argument has been echoed by Isaac Sindiga who has pointed out that: "each cultural group handles its medical problems in a particular way, and has its own world-view, traditions, values and institutions which have developed over time to handle disease and illness. Also, each culture has its own disease aetiologies, medical terminologies and classification, medical practitioners, and a whole range of pharmacopoeia" (1995: 20). The implication of Sindiga's observation is that one cannot postulate, with logical impunity, a particular healthcare practice as engendering eternal truths that are applicable everywhere regardless of cultural context.

In the study the dichotomy between the Western practice of medicine and medical research was established. It is clear that while Western medical practices tend to see disease in terms of the functioning of the body, and on the other hand, in the African context, disease is understood in terms of a causal relationship between the "visible" and "invisible world" (Sindiga, 1995). In the same vein, Gloria Waite has suggested that an "African understanding of disease should be seen as a medico-religious in contrast to a biotechnical medical system" (Waite 1992: 214). Shutter (2001, 131-132) argued that "a healthcare practice that is purely scientific in its conceptualisation and treatment of disease would inevitably fail to embrace the spiritual dimension of human sickness". Within the African traditional context such a healthcare practice is construed as an exercise in dehumanisation. With its strong emphasis

on the idea of the dignity of the human body, African bioethics view Western medical practices as problematic because of the way in which the body is treated in such a way that renders the person insentient. In an African cultural context where a human being is viewed holistically, a healthcare practice that places emphasis on merely repairing human organs is inadequate because it cannot give a comprehensive view of disease and causation. Janzen (1982: 4) states that “it could be argued that it is because of the African holistic view of healing that is part of the reason why many Africans have resorted to complement Western medicine with that which is provided by the African traditional doctor”. This in turn creates the room to implement everything including informed consent process which is ontologically Western.

However, all the participants did not fully go with the above argument. Some point out that with the exposure to Western form of education, one begins to think individually and this create a room for the understanding of informed consent in an individualistic form. The shortcomings for this assertion though are that with the whole movement of decolonisation in Africa, it is arguable that educational systems in Africa are beginning to take into context key traditional and cultural African values. Here, it is clear that education will not be able to resolve the existing conflict between informed consent and cultural African values and norms of behaviour. The ever-growing conflict has led to the emergence of indigenous population developing their own code of ethics and the San happen to be the first in Africa. The section below will present the decisions about the findings on perceptions of researchers in UKZN concerning the San code of ethics.

5.3. San Code of Ethics

In March 2017, the San people of South Africa produced the first research ethics designed by an indigenous African population. This was motivated by the fact that numerous studies had been conducted among the San group, and these studies were perceived negatively by the San group. The San leaders articulate that while the researchers were ethical in following the general legal principles of obtaining gatekeepers letter from the government, and approval from the universities, the consent process was inadequate from their point of view. According to Daley, the researchers did everything legally, by obtaining appropriate ethical approvals from the Namibian government and their respective universities. In addition, they obtained verbal consent from the participants through the help of a translator but the San leaders were not pleased because they were not consulted about the research and they questioned the

verbal process of obtaining consent from the participants (Daley 2017). This gave the San leaders the perception that researchers are only interested in fulfilling the legal process of obtaining consent and by doing this, Rachels (1986) has argued that researchers reduced research participants to objects of research not subjects (Rachels 1986). The San demanded that they require respect, honesty, justice and fairness, and care from researchers who come to them for research. They also demand that their leaders and community members be involved in the consent process to reduce exploitation and disrespectful act on their culture, environment and the people.

However, these demands as discovered in the research are not very different from what other declarations and ethical codes already articulate. It is more like an integrated communal form of the four principles of medical research and practice. The San advocates for respect and in the four principles, there is principle of respect for autonomy. In other words, the San are saying we want our community and the people to be treated with respect. The same goes with beneficence, non-maleficence and justice. They advocate that they do not want to be exploited and that benefit should be shared equally and that researchers should care about what they have, what they are doing and who they are. This is similar to what is presented in the declaration of Helsinki section 25 (p5); it states that “participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees”. This gives room for community and family involvement in the consent process.

However, the San are of the idea that community consent and involvement in research reduces exploitation and thus, presuppose individual consent. The research discovered the ethical code designed by the San is appropriate for their community. Furthermore, the implementation of the code will engender medical practice in Africa as it will advocate for the communal consent process that will allow Africans to identify with and internalize medical research and practice in Africa. It will further motivate other African communities to come together and deliberate using the key and common African cultural norms of behaviour and belief systems to develop a research code that is applicable in Africa.

However, it will be necessary to note that the implementation of the San code might develop a dilemma, and this is actually the dilemma that this research is exploring. The current practice of medical ethics is rooted in the Western-European tradition as postulated earlier in

the research. This is because when research is conducted in Africa or when ethics committees are reviewing a research protocols, their primary focus is on the individual. If a research proposal/protocol is focusing on an individual and the researcher is planning to go and research among people who do not think individually there is bound to be a conflict.

The research discovered that another source of conflict with the San code might be in the aspect of community consent as oppose to the individual consent. This is because if an individual decides against the decision of the community, it might lead to “ostracization” of the individual from the community if it is not managed properly. For instance, a community, using their own code may decide that the research is necessary for the development of their community and that participants should take part because it is safe. However, within that community a particular participant may decide that he or she will not take part, this might lead to discrimination against that individual in the community as it may be perceived that he or she does not have the benefit of the community at heart. There could be a conflict between the right of the individual and the rights of the community. In this case, if an approach is to be developed, it will be necessary to develop an approach that will take into account the community as well as the individual right. This is where the development of an alternative approach to ethical decision making become appropriate.

5.4. Alternative approach

This study confirms the findings of other studies that biomedical research is adopting a bottom-up approach of moral reasoning. As the traditional monoistic moral theories like consequentialism, utilitarianism and deontology ethics appeals to an abstract universal notion of personhood and could be used as means of intellectual and cultural imperialism. Biomedical ethics on the other hand deals with real people in particular situations, i.e. particular persons in particular contexts or contextualized persons. Biomedical ethics is also rooted in culture. If there is no cultural practice and way of life, there will be no biomedical ethics. This is because the four assumed globally accepted biomedical ethical principle are autonomy, beneficence, non-maleficence and justice formally presented by Beauchamp and Childress in 2013, to address biomedical issues in the West and this is why they are rooted in the Western-European traditions and the Western-European world is different from Africa.

In reality, biomedical ethics are assumed to be culture-free and applicable across cultures because its elements and principles are based on culture and traditions (Chukwuneke, Umeora, Maduabuchi and Egbunike 2014).

In addition, this research is opting out of monoistic approach and opting, instead, for a pluralistic one because of its compatibility with the idea of multiculturalism. As Wildes and Kevin (2007) argue, culture has a deep relationship with morality. The concept of multiculturalism links directly to the reason why morality should be pluralistic and account for a diversity of belief and value systems. They assert that morality encompasses the moral practice, which is embedded in culture, which we see as a way of life. Ethics seeks to examine those practices and moral systems that are embedded in cultural practices. Advocating for a multicultural society, which a lot of people do nowadays, will be synonymous to advocating for a morally pluralistic society.

As it is seen above, it is clear that there is a conflict, an ethical dilemma and in any case of ethical disagreement or clash one needs an ability to recognise and identify the problem as well as debate it within a wider framework of agreed-upon rules, established principles and ethically relevant considerations. The differences in cultural and moral values and seemingly intractable problems within the traditional ethical theories indicate the need to look for an alternative moral approach and becomes of vital importance in this study (Brody, 2003). Adopting Ross' model of ethical reasoning as a lens, it may be argued that it is possible to develop suitable methods to deal with the potential conflict between the application of informed consent in Africa and the African cultural beliefs and norms of behavior without undermining African traditional values and belief systems. The central notion of the alternative approach by Ross (1930) is *Prima Facie duties* – which literally means from the first sight which is different from absolute duties that hold in all circumstances or conditional duties (Beauchamp & Childress, 2013).

Ross argued that “*Prima Facie* suggests in this approach that one is speaking only of appearance which a moral situation presents at first sight, and which may turn out to be illusory, whereas what he is speaking of is an objective fact involved in the nature of the situation or more strictly in an element of its nature, though not as duty proper does, arising from its whole nature” (1930:20). For example, is it your duty to keep a promise when you may be in a position to avert a serious accident by failing to keep it? There are two *Prima Facie* duties here; the first is to keep a promise and the second is to relieve distress. The circumstances in the particular case can make the latter a greater duty, looking at the seven principles of *Prima Facie* duties which are the guidelines in decision making. These are fidelity, reparation, gratitude, justice, self-improvement, non-maleficence, and beneficence.

Ross' model is preferred in regard to this research because the *Prima Facie* duties stem from relationships and from the analogy in chapter two, it is clear that African notion of person is relational. Although, Ross' model is Western, it gives credit to relationship, obligation and responsibility. Thus Ross' model seems to be the most suitable model to follow (Ross 1930).

From the presentation of data, it is clear that there is an obvious difference between the Western practice of biomedical ethics and African practice of biomedical ethics. In that case, the Western informed consent processes are not compatible within African cultural norms but that does not mean that there is no way it could be adopted to suit the situation in Africa and it does not also mean we do not need it at all. However, it was discovered in the research that while dealing with African communities, the researcher has to take into account the environment, the spirituality, and the culture of the people. This is similar to what the San are advocating for. They are arguing for respect, honesty and truthfulness and an appreciation of the fact that in African belief systems a person is not a person on his or her own. The individual is a person through the community and by default the person becomes part of a community and whatever happens to the person directly affects the community (Menkiti 1984).

Thus, as Ross argued, intuitively a researcher who is researching in Africa should know that what is paramount should be that the way informed consent is practised in the West is different from how it should be in Africa. It should come at first sight to the researcher that informed consent in Africa should take all the traditional values and belief systems of Africans into account. He/she should be aware that Africans act as a group and thus the interest of the group is more important. So, in the context of Africa, it will be necessary to involve the community in the consent process.

5.5. Summary

Many ethics committees require written informed consent and the use of a consent form, which describes the purpose and procedures of the study and its potential risks and benefits of participation; it explains that participation is voluntary and that subjects can withdraw at any time; and provides information about maintaining subject privacy and confidentiality of research data. Consent forms and other information provided to participants should be in a language understandable to the participant or to the parent or guardian if the participant is a

child⁷. Yet an individual-based consent model and the use of written consent documents may be problematic in countries where norms of decision-making do not emphasize individual autonomy and where there are nonliterate populations. Thus, several guidelines and reports on research ethics endorse the use of community approval and verbal consent for research in countries where cultural values and practices emphasize oral rather than written agreements and where community leaders, elders, and tribal chiefs play an important role in decision-making⁸.

This brings to light the fact that Bio-Medical Ethics is on a quest for its authenticity in Africa. This is because the progress of Bio-Medical Ethics in Africa would have been easily possible if the principles of Bio-Medical Ethics were not rooted in the Western-European traditions. It will not be easy for Africans to separate themselves from their traditional African thought elements for the Western bio-medical superimposition. For instance it is estimated by Dr Eleanor Ross in her inaugural lecture (June 2010) that there are between 250 000 and 400 000 traditional healers in South Africa, and 28 000 medical doctors. Eight out of every 10 black South Africans are believed to rely on traditional medicine alone, or in combination with Western medicine. This is because traditional healers occupy esteemed positions within many indigenous South African cultures as they are consulted for a wide range of physical, social and emotional problems and are often expected to assume the multiple roles of medicinal healer, physician, priest, psychiatrist, advisor, teacher, diviner and herbalist and this is what the traditional people of Africa expect when they go to the hospital.

The Western-European concept of individual respect for autonomy which is the central tenet in bio-medical ethics looking at informed consent conflicts with African cultural values and norms. The concept of *Ubuntu* (isiZulu) and *Ukama* (Shona) which are among the few core African concepts advocates for a form of wholeness that come through one's relationship and connectedness with the other people in the society.

Therefore, African communitarian ethics focus on the interests of family/community instead of an individual, hence collective decision-making process takes over individual consent.

⁷ Department of Health and Human Services. Protection of Human Subjects. 45 CFR 46.

⁸ Nuffield Council of Bioethics. National Bioethics Advisory Commission. Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries. NBAC; Bethesda, MD: 2005. The ethics of healthcare in developing countries: A follow-up discussion paper. 2001

These considerations suggest that practitioners of Western biomedical ethics in Africa may encounter intractable ethical problems (moral dilemmas) that might be generated by some of the traditional values, practices, rituals and taboos that still govern people's behaviour and relationships. Thus there is need to develop an alternative approach that is more cultural sensitive. If the above is done, the growth of medical practice and research will be feasible because medical and research principles will be more culturally sensitive and Africans will be able to identify with it. This will also allow Africans to internalize and benefit from the advancement in medical science and this could contribute to the reduction in mortality rate in Africa.

5.6. Conclusion

Bioethics cannot be universalized or globalized because it should be aware, cognizant, sensitive and relevant in all cultures and traditions. The existence of different values/morals that vary from community to community and from different societies within communities will facilitate the failure of global bioethics. Thus, it will be difficult to have a global concept of bioethics without considering cultural response to ethical issues because different communities have different values and morals that guide them. According to Chukwuneke, Umeora, Maduabuchi and Egbunike 2014 the four commonly used principles of bioethics are autonomy, beneficence, nonmaleficence and justice and are based on a particular tradition and culture. Beneficence/nonmaleficence requires us to maximize possible benefits, while minimizing possible harms and consequently secure the well-being of others by refraining from harming them. Justice is concerned with the fair selection and distribution of the burdens and benefits of the research among participants, while autonomy which is the central concept of informed consent gives individuals the right to self-actualization and decision-making. This can be very successful in the Western world that is more individualistic but fails in Africa that is more communitarian.

For instance a pregnant woman who is about to undergo an operation to facilitate the delivery of the child will require consent before the operation is carried out and the question is whose consent will be needed? In an African concept the child is not only the woman's but also the man's (husband's family) thus if the woman makes the decision alone it might cause a very big family conflict whereas in the Western world the woman can make an autonomous decision concerning the child and her health without really considering the individuals that will be affected by the decision. Currently, these Western concepts of individualism is what

the concept of autonomy in bioethics advocates for. Thus when it is applied in Africa it produces a conflicting situation and in some cases this conflicting situation facilitates the denial of the right for the appropriate group to consent before their children or relations are used as a research participants.

Finally, Bioethics principles and framework in Africa though may take cognizance of the bioethics principles as postulated by Western philosophy but with different approaches and practices. This is because of the difference in understanding of personhood and social interactions existing within the various communities in Africa compared to what is typically adopted in Western communities.

Consequently, African bioethics by its application has its own framework based not entirely on the method of practice and application of what the Western bioethics regard as global bioethics. The four bioethics principles; Autonomy, justice, beneficence, and non-maleficence if followed and obeyed are good. Generally speaking everybody will agree that autonomy is good, that justice is good, that it is good to do good, and that it is good not to inflict harm.

However, what constitutes the good in various circumstances cannot be universalized because we have different cultural practices that influence deeply what we do and who we are. Thus there is still a problem, a conflicting situation in the practice of the principle of biomedical ethics as well as informed consent in Africa. This is because all the avenues have not fully been explored because of the limited nature of the project although there are avenues for further investigation and analysis.

The above presented data and model does not mean that once this is applied, every possible conflict in Africa in terms of informed consent is eradicated. The time and structure of the research did not allow the researcher to explore more into the conflict between the South African constitution and the traditional values and belief system of the people. The research did not also get empirical data from African indigenous population, it only relied on the San code of ethics. Finally, an input from African traditional doctors will also contribute to the conclusion engendering medical practice in Africa. These are avenues for further research and it come out from the investigating done in the research.

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APPENDIX I

Interview Guide

thank you very much for agreeing to speak with me about your experience of medical research in African. I am Francis Fabian Akpa-Inyang working on a research titled; Southern African traditional values and belief systems and informed consent process in biomedical ethics: perceptions of the San code of ethics. Before we start I will like to know your gender, age if you are comfortable, race and your research specialty.

1. What are the important aspects of an ethical research project for medical researchers
2. What are the strategies you adopt as a principle investigator to meet these criteria?
3. Are there any limitations in the application of these criteria to the general population of Africa?
4. What is your opinion on informed consent in Africa?
5. How successful is the application of the principle of autonomy in the general population of Africa?
6. Are you aware that the San people designed a new code of ethics? (if no I will explain)
7. What do you think about the San code of ethics?
8. What are the possible contributions of the San's code of ethics to medical research and practice in Africa?
9. Looking at Ross' theory of *Prima Facie* duties, do you think that adopting a principle that is more cultural sensitive will engender the relationship between researcher and research participants?
10. Is it possible to reconcile the concept of informed consent with the traditional African values and norms of behaviour taking the San code of ethics as a case?
11. What is the suitable method for the recognition of arising moral conflicts and controversies and their resolution with respect to traditional values and beliefs?

APPENDIX II

UKZN HUMANITIES AND SOCIAL SCIENCES RESEARCH ETHICS COMMITTEE (HSSREC)

INFORMED CONSENT

Information Sheet and Consent to Participate in Research

Date: 15th May, 2017

Greeting: Dear Researcher,

My name is Francis Fabian Akpa-Inyang a master's student in The School of Build Environment and Developmental Studies, Department of Population Studies.

Contact: 0604147582

Email: francisediomo@gmail.com

You are being invited to consider participating in a study that involves 'Southern African traditional values, belief systems, and the informed consent process in biomedical research: Perceptions of the San's Code of Ethics'. The aim and purpose of this research is

1. To explore the understandings of the nature of the principle of informed consent among biomedical researchers.
2. To explore the possible conflicts that will arise in the application of the principle of medical ethics to the general population in Africa...
3. To determine the reasons and grounds for conflicts and controversies that its application can engender in the context of African traditional value and belief systems.
4. To argue for the use of an alternative approach to explore the concept of informed consent in doctor patient relationship in Africa.

The study is expected to enroll 12 medical researchers in University of KwaZulu-Natal and Caprisa. It will involve interview sessions. The duration of your participation if you choose to enroll and remain in the study is expected to be 1 hour. The study is funded by the department of Population Studies in University of KwaZulu-Natal.

The study do not involve any risks and/or discomforts. The hope is that the study will create a new biomedical principle for medical practitioners and researchers that will be applicable for African people in Africa.

This study has been ethically reviewed and approved by the UKZN Humanities and Social Sciences Research Ethics Committee (approval number _____).

In the event of any problems or concerns/questions you may contact the researcher at

School of Build Environment and Development Studies,
Department of Population Studies,

Howard College Campus,
Shepstone Building Level 7,
Durban
4000
KwaZulu-Natal, South Africa
Cell:+27604147582
Email:francisediomo@gmail.com

or the UKZN Humanities & Social Sciences Research Ethics Committee, contact details as follows:

HUMANITIES & SOCIAL SCIENCES RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus
Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604557- Fax: 27 31 2604609
Email: HSSREC@ukzn.ac.za

Participation in this research is voluntary and participants have the freewill to withdraw participation at any point. In addition, at the event of refusal/withdrawal of participation the participants will not incur penalty or loss of treatment or other benefit to which they are normally entitled. The participant can terminate participation in the study at any time and it will not incur any consequence. The researcher will terminate a participant from the study if and only if the participant is not a medical researcher or practitioner.

There will be no cost incurred by the participant as a result of participation in the study and there will be no incentives or reimbursement for participation in the study.

To protect confidentiality of personal/clinical information, I have decided that the digital recordings and electronic transcripts will be kept in a password protected folder on my personal computer. The hard copies will be locked in a filing cabinet. No identifying information (such as consent forms) will be kept with the digital or hard copies. On completion of the project, the research data (all electronic and hard copies) will be stored in the supervisor's office for five years after which it will be permanently destroyed.

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CONSENT (Edit as required)

I _____ have been informed about the study entitled 'Southern African traditional values and belief systems and the informed consent process in biomedical research: Perceptions of the San's Code of Ethics' by Francis

Fabian Akpa-Inyang from the School of Build Environment and Development Studies, department of Population Studies.

I understand the purpose and procedures of the study.

I have been given an opportunity to answer questions about the study and have had answers to my satisfaction.

I declare that my participation in this study is entirely voluntary and that I may withdraw at any time without affecting any of the benefits that I usually am entitled to.

If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher at (provide details).

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

HUMANITIES & SOCIAL SCIENCES RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus

Govan Mbeki Building

Private Bag X 54001

Durban

4000

KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604557 - Fax: 27 31 2604609

Email: HSSREC@ukzn.ac.za

Signature of Participant

Date

**Signature of Witness
(Where applicable)**

Date

**Signature of Translator
(Where applicable)**

Date